IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
DAYTON DIVISION

DAYTON AREA CHAMBER OF COMMERCE, *et al.*, *Plaintiffs*, v. XAVIER BECERRA, *et al.*, *Defendants*.	**No. 3:23-cv-00156-MJN-PBS** **Judge Michael J. Newman** **Magistrate Judge Peter B. Silvain, Jr.**

PLAINTIFFS' COMBINED OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, CROSS-MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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federal legislation of significant concern to businesses in both the pharmaceutical industry and beyond, including in the Dayton metropolitan region.

Even if this Court were to reach the government's waived venue objection and to find that the Dayton Area Chamber cannot support venue, the proper remedy would be transfer to the Eastern Division of this District, not dismissal. *See* 28 U.S.C. § 1406(a). Venue in this District is not predicated solely on the Dayton Area Chamber; another Plaintiff—the Ohio Chamber of Commerce—also resides in this District. *See* 28 U.S.C. § 1391(e)(1).

Plaintiffs' "excise tax" claims are redressable in this suit. The government's assumption that HHS and CMS have nothing to do with enforcing the "excise tax" is flatly contradicted by the IRA, *see* 26 U.S.C. § 5000D, 42 U.S.C. §§ 1320f(a), 1320f-5(a)(6), and CMS's own guidance, see June 2023 Revised Guidance on Medicare Drug Price Negotiation Program at 91–92, 167, which confirm that HHS and CMS play an important role in administering the "excise tax." Plaintiffs' requested relief against HHS and CMS is at least "likely" to redress their injuries, *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

The government's invocation of the Anti-Injunction Act is unavailing. These claims satisfy both equitable exceptions under the AIA. Plaintiffs would suffer irreparable injury if not permitted to challenge this "tax," and it is clear that the "tax" will not survive scrutiny on the merits. *See Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1, 7 (1962). In addition, Plaintiffs lack an alternative way to challenge the validity of the "tax." *South Carolina v. Regan*, 465 U.S. 367, 373 (1984). Especially given Congress's own recognition that this "tax" will not raise any revenue to begin with, the Court should not construe the AIA to bar the only avenue for challenging its constitutionality.

The unprecedented and unaccountable structure of the IRA's price-control program violates the nondelegation doctrine and the separation of powers under both binding precedent and the original understanding of the Constitution. The government fails to identify any

"intelligible principle" to restrain HHS's discretion to set prices as low as it wants. Even the precedents cited by the government confirm that minimum standards of fairness and opportunities for judicial review are necessary to constrain agency discretion and protect private rights. *See, e.g.*, *Fed. Power Comm'n v. Hope Nat. Gas Co.*, 320 U.S. 591, 602 (1944); *Yakus v. United States*, 321 U.S. 414, 421 (1944). The IRA, in contrast, gives HHS "virtually unfettered" discretion to upend the pharmaceutical industry, *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 542 (1935), a violation of the nondelegation principle that is exacerbated by the IRA's sweeping and unprecedented prohibition on judicial review, *see* 42 U.S.C. § 1320f-7; *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946).

Strikingly, the government does not dispute that the IRA's anomalous procedures fail to satisfy the due-process requirements set forth in *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587 (6th Cir. 2001), and *Mathews v. Eldridge*, 424 U.S. 319 (1976). As the government has effectively conceded, if those tests apply—and they do—the IRA fails.

The government's extreme position that the IRA need not satisfy any due-process requirements whatsoever is inconsistent with canonical procedural due process precedents such as *Eldridge*. But even if the government were correct that due-process requirements evaporate whenever participation in a government program is voluntary, and even assuming that participation in Medicare and Medicaid is voluntary, the government's cited authorities prove nothing about Plaintiffs' due-process challenge *to the IRA*. As in *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519 (2012), there is a difference between an ordinary alteration to a program and a dramatic change that transforms the nature of the program. The IRA fundamentally transforms Medicare and Medicaid and coerces manufacturers by weaponizing their reliance on Congress's longstanding promises. None of the government's attempts to distinguish *NFIB* and repudiate the unconstitutional-conditions doctrine is persuasive.

Even apart from the IRA's coerciveness under *NFIB* and the unconstitutional-conditions doctrine, manufacturers are legally required to remain in the price-control program during the statutory window of 11 to 23 months before a withdrawal from Medicare takes effect. CMS issued non-binding guidance in response to litigation that purports to dispense with that statutory requirement, but

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INTRODUCTION AND SUMMARY OF ARGUMENT

The government's brief continues its quest to rewrite the IRA into a statute that it believes it can defend. The government portrays the IRA's unprecedented price-control regime as just an invitation to engage in an ordinary transaction with an ordinary market participant. In reality, the IRA throws down the gauntlet with a set of extraordinary demands: give HHS confidential, commercially sensitive information that you would never willingly share with any ordinary counterparty; turn over your valuable and hard-earned property at whatever prices HHS sets in its standardless, unreviewable discretion; and then—adding insult to injury—tell the public you "agree" those prices are "fair" and that any higher prices are unfair. Congress knew manufacturers would never willingly agree to those terms, so Congress left them "with no real option but to acquiesce," *Nat'l Fed'n of Indep. Bus. v. Sebelius* (*NFIB*), 567 U.S. 519, 582 (2012), by backing the IRA's demands with an "excise tax" penalty of up to 1,900% for "noncompliance" and a threatened cut-off of nearly half the prescription drug market. Despite the government's efforts, no amount of ink spilled in a brief can fix that regime's fatal constitutional defects.

The government first tries to avoid the merits with a series of procedural objections. It recycles its contention that Plaintiffs' claims require the individual participation of members, but that contention had no support at the preliminary-injunction stage and still has none. And the most notable thing about the government's procedural objections is what's missing, as the government has abandoned its lead defense: its claim that Plaintiffs' members lack an injury-in-fact. In contrast, for the first time, despite no change in Plaintiffs' asserted basis for venue since June 2023, and despite already having moved to dismiss under Rule 12, the government objects to venue on the ground that the IRA's massive nationwide impact will somehow pass over the Dayton metropolitan region and the IRA therefore has no relation to the Dayton Area Chamber's goals of fostering a favorable climate for business. The government's attempt to portray the Dayton area as an isolated

island—and its suggestion that it knows better than the Dayton Area Chamber what matters to its members—fail. Plaintiffs have every right to bring their suit in this Court, and the government's belated objection to venue is as meritless as it is unpreserved. Finally, the government argues that this Court lacks jurisdiction over Plaintiffs' constitutional challenges to the IRA's astronomical "excise tax." But contrary to the government's insistence that Plaintiffs should have sued the IRS too, an injunction against HHS would provide redress. And the Anti-Injunction Act is no bar to Plaintiffs' challenges to the "excise tax" given the unique nature of that "tax."

The government fares no better on the merits. First, with respect to Plaintiffs' separation-of-powers and nondelegation claim, the government fails to identify any "intelligible principle" that can restrain HHS's discretion to set prices as low as it wants. The government also tries to deny the relevance of the IRA's dearth of procedural safeguards, including its prohibitions on judicial and administrative review. But the Supreme Court and lower courts have repeatedly recognized the importance of such protections for separation-of-powers and nondelegation analysis. And the government's cited cases only highlight how anomalous the IRA's price-control regime is in failing to provide judicial review or a statutory standard of fairness or reasonableness to prevent arbitrary and confiscatory pricing.

That lack of basic, time-honored procedural safeguards also dooms the IRA's price-control regime on Plaintiffs' related but independent due process claim. For decades, Congress induced pharmaceutical manufacturers to participate in Medicare and Medicaid with promises of market-based pricing and non-interference in private negotiations. In reliance on those commitments, manufacturers invested tens of billions of dollars in the long, arduous process of developing innovative new prescription drugs. Yet in the IRA, Congress pulled a 180-degree turn. While the government continues to pretend that the IRA is just another add-on to Medicare and Medicaid,

that is the same move it tried—and that the Supreme Court roundly rejected—with the Medicaid expansion in *NFIB*, 567 U.S. at 581–85. Like the Medicaid expansion, the IRA is not a routine Medicare amendment or a run-of-the-mill condition on participation. It is "in reality a new program" that fundamentally transforms the basic bargain between manufacturers and the government. *Id.* at 582. "Previous [Medicare and] Medicaid amendments simply do not fall into the same category as the one at stake here." *Id.* at 585. As such, like the Medicaid expansion in *NFIB*, the IRA's price-control program must be analyzed on its own terms—not, as the government insists, by reference to snippets of language in decades-old cases addressing provisions that bear no resemblance to the IRA. Whether or not Medicare or Medicaid were voluntary before the IRA, under *NFIB* and the unconstitutional-conditions doctrine *the IRA* is coercive.

To further mask the coercive nature of the program, the IRA violates manufacturers' First Amendment rights by forcing them to engage in compelled speech. The government argues that this speech is merely incidental to the price-control program. But Congress could have imposed price controls without speech controls (as it has done many times), so the compelled-speech requirements serve no legitimate government interest. Their only purpose is to enlist manufacturers in the government's public-relations campaign to portray the IRA as voluntary and "fair."

As for the IRA's so-called "excise tax," it is an excessive fine by another name. The IRA itself makes clear that the "tax" is a penalty for "noncompliance," and the up-to-1,900% rate is indefensible, especially as a punishment for wishing to sell lawful, life-saving medicines at market prices. Indeed, a sure sign that the government knows the "excise tax" is excessive is that the government rewrites it as if it were orders of magnitude lower. But the penalty is every bit what Congress meant it to be: a weapon of mass extortion. Because the penalty finds no support in any

of Congress's enumerated powers, it not only violates the Excessive Fines Clause but exceeds the limits of Congress's legislative authority.

In the end, there is no escaping the conclusion: the IRA's price-control program is unprecedented and unconstitutional.

ARGUMENT

I. The Government's Procedural Objections Are Meritless.

A. Plaintiffs' Requested Relief Does Not Require the Participation of Individual Members.

In its first motion to dismiss, the government raised a slew of standing and ripeness arguments. The government told the Court that Plaintiffs had no Article III injury because the IRA's price controls might leave their members better off. Dkt. 33 at 1; *see id.* at 7–10. It maintained that Plaintiffs' claims were not ripe because (according to the government) no injury would occur "until 2026." *Id.* at 1–2; *see id.* at 18–20. And with respect to the three-prong associational standing test, the government argued that Plaintiffs could not show that any individual member had standing (prong 1) and that, because some companies had filed separate suits, the relief requested here requires the participation of individual members (prong 3). *See id.* at 11–18.

The government has abandoned all but one of those arguments. The lone exception is the government's argument regarding the third prong of the associational standing test, which it reprises in substantially the same form. *Compare* Dkt. 33 at 15–18 *with* Dkt. 71 ("Gov't Br.") at 17–20. That argument remains illogical and legally baseless. As this Court observed the first time around, "Defendants' assertion—that the existence of other pending cases requires the participation of individual members—is unsupported by citations." *Dayton Area Chamber v. Becerra* (*Chamber I*), No. 3:23-cv-156, 2023 WL 6378423, at *7–8 (S.D. Ohio Sept. 29, 2023). It

still is: the government has not found any authority to support its radical new limit on associational standing.

The third prong of the associational standing test "bars a suit 'when *the claim asserted* [or] *the relief requested* requires the participation of individual members in the lawsuit.'" *Id.* (quoting *United Food & Com. Workers Union Loc. 751 v. Brown Grp., Inc.*, 517 U.S. 544, 546 (1996) (emphasis added)); *see Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 344 (1977). The inquiry focuses on the nature of the claim and the type of relief requested. *See, e.g.*, *Fednav, Ltd. v. Chester*, 547 F.3d 607, 615 (6th Cir. 2008) ("[N]one of the Associations' claims or their requested relief . . . require the participation of their members in the lawsuit" because they seek only injunctive or declaratory relief and "do not, for example, seek individualized damages that only a member could obtain"); *Bldg. & Constr. Trades Council v. Downtown Dev., Inc.*, 448 F.3d 138, 150 (2d Cir. 2006) ("[T]he third prong of *Hunt* concerns claims that would require 'individualized proof,' such as claims for damages"). As this Court observed, "the general rule is that individual participation of members 'is not normally necessary when an association seeks prospective or injunctive relief for its members' but may be required when the association is seeking damages." *Chamber I*, 2023 WL 6378423, at *7–8 (quoting *United Food*, 517 U.S. at 546). "When a 'suit raises a pure question of law' and [consideration of] the 'individual circumstances' of each member is not required to render a decision, individual participation of the members is not required." *Id.* (quoting *Int'l Union, United Auto., Aerospace & Agric. Implement Workers v. Brock*, 477 U.S. 274, 287 (1986)).

The Supreme Court and the Sixth Circuit have consistently interpreted the third prong in precisely that manner. *See, e.g.*, *Int'l Union*, 477 U.S. at 287 (considering whether "the fact and extent of injury would require individualized proof" (quoting *Warth v. Seldin*, 422 U.S. 490, 515–

16 (1975))); *United Food*, 517 U.S. at 546 ("*Hunt* held that 'individual participation' is not normally necessary when an association seeks prospective or injunctive relief for its members, but indicated that such participation would be required in an action for damages to an association's members"); *Universal Life Church Monastery Storehouse v. Nabors*, 35 F.4th 1021, 1040 (6th Cir. 2022) (no "individual participation" necessary "to secure an injunction"); *Barry v. Lyon*, 834 F.3d 706, 716 (6th Cir. 2016) (same); *Fednav, Ltd.*, 547 F.3d at 615 (same); *Sandusky Cnty. Democratic Party v. Blackwell*, 387 F.3d 565, 573 (6th Cir. 2004) (per curiam) (same). To Plaintiffs' knowledge, no court has ever applied the third prong in the manner now proposed by the government.

Plaintiffs' suit raises pure questions of law regarding the IRA's facial constitutionality, and Plaintiffs seek only prospective relief. Unlike damages claims, which typically depend on the "fact and extent of injury" to each individual member of the association, the injunctive and declaratory relief Plaintiffs seek does not require "individualized proof." *Int'l Union*, 477 U.S. at 287 (quoting *Warth*, 422 U.S. at 515–16). Per this Court's suggestion, Plaintiffs made that limitation on the scope of their requested relief even more explicit in their amended complaint. *See Chamber I*, 2023 WL 6378423, at *8; Dkt. 57 ("FAC") ¶ 60. Plaintiffs' claims "are thus properly resolved in a group context." *Hunt*, 432 U.S. at 344.

Nonetheless, even though Plaintiffs meet all of the established requirements of the associational standing test, the government insists that standing is "unworkable" because some of Plaintiffs' members have brought their own separate suits challenging aspects of the IRA on various grounds. Gov't Br. 17. The government asserts that allowing this suit to proceed would somehow undermine goals of "administrative convenience and efficiency" served by associational standing. *Id.* (quoting *United Food*, 517 U.S. at 557). As an initial matter, the reference to

"administrative convenience and efficiency" in *United Food* has nothing to do with the government's proposed ban on associational standing when some members file separate suits. The "matters of administrative convenience and efficiency" the Court identified in *United Food* were related to the distinction between damages claims and prospective relief. 517 U.S. at 556–57. For example, the Court noted that the third prong "may guard against the hazard of litigating a case to the damages stage only to find the plaintiff lacking detailed records or the evidence necessary to show the harm with sufficient specificity" or "hedge against any risk that the damages recovered by the association will fail to find their way into the pockets of the members on whose behalf injury is claimed." *Id*. Those concerns have no relevance here. Moreover, even taking the government's argument on its own terms, dismissing this suit and forcing Plaintiffs' members to file even more standalone suits would not enhance convenience or efficiency for anyone.

The government's worry that "gamesmanship and chaos" might result from conflicting judgments is misguided and overblown. Gov't Br. 18–20. The government suggests that different courts "might" eventually reach different conclusions on the merits of the same claims and that, if so, some of Plaintiffs' members "might" seek to follow the more favorable ruling, and the parties "might" then have to litigate "complex questions of preclusion." *Id.* at 19. This chain of hypothetical future possibilities is no basis to deny Plaintiffs associational standing here and now. If a mere "risk" of "follow-on litigation over preclusion" were enough to defeat associational standing, *id.* at 20, associational standing would cease to exist. That may be the government's true hope, but it is not the law: when the government asked the Supreme Court in *International Union* to abolish associational standing, the Court refused. *See Int'l Union*, 477 U.S. at 288–90 ("[The government's] presentation has fallen far short of meeting the heavy burden of persuading us to abandon settled principles of associational standing"). There is no basis to impugn Plaintiffs'

members by suggesting that they will engage in inappropriate "gamesmanship," and there is no reason to think that, if any preclusion questions ever do arise, courts would be unable to resolve them at that time. As Plaintiffs have explained, and as common sense would suggest, any members who have filed separate suits will be bound by judgments in those suits. Dkt. 50 at 12, 17–18. The government also does not dispute that the other suits largely entail different sets of claims, so even if all the cases proceed to judgment, the judgments would not necessarily rest on the same grounds.

That one more company recently filed its own suit, *see* Gov't Br. 20, changes nothing. "[A]n organization can achieve representational standing if its members, *or any one of them*, are suffering immediate or threatened injury as a result of the challenged action." *Ball ex rel. Burba v. Kasich*, 244 F. Supp. 3d 662, 682 (S.D. Ohio 2017) (emphasis added) (quotation marks omitted) (citing *Warth*, 422 U.S. at 511). Here, in addition to the direct and imminent impact on AbbVie and Pharmacyclics, this suit advances the interests of a broad cross-section of Plaintiffs' pharmaceutical and other industry members, including manufacturers that will be ensnared by future rounds of IRA price controls. That the government prefers to pick off companies one by one, rather than let them "band together" and litigate as members of an association, *Int'l Union*, 477 U.S. at 290, does not change settled associational standing doctrine. Under that doctrine, Plaintiffs' facial constitutional challenges seeking purely prospective relief are the classic example of claims that may properly be litigated by associations.

B. The Government's Belated Venue Argument Is Waived and Meritless.

While abandoning most of the arguments it made in its first motion to dismiss, the government seeks to raise a new argument that it *failed* to make in that motion. The government contends, for the first time, that venue is improper because this litigation is supposedly not germane to the purposes of the Dayton Area Chamber. Gov't Br. 11–14. The government waived that argument by electing not to raise it in its prior motion to dismiss. And even if that argument had

been preserved, it would fail because the Dayton Area Chamber easily satisfies the "undemanding" germaneness requirement. *Nat'l Lime Ass'n v. EPA*, 233 F.3d 625, 636 (D.C. Cir.), *as amended on denial of reh'g* (Feb. 14, 2001) (quoting *Humane Soc'y v. Hodel*, 840 F.2d 45, 58 (D.C. Cir. 1988)).

1. The Government Waived Its Venue Argument by Failing to Raise the Argument in Its Initial Motion to Dismiss.

The government had every opportunity to challenge venue based on the germaneness requirement in its initial motion to dismiss. Having failed to make the argument then, the government cannot press it now. Once a party makes a motion under Rule 12, it "must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion." Fed. R. Civ. P. 12(g)(2); *see Means v. U.S. Conf. of Cath. Bishops,* 836 F.3d 643, 648 (6th Cir. 2016) ("Rule 12(g)(2) . . . requir[es] a party making a Rule 12 motion to raise all defenses or objections available to a party at the time of the motion"). As the Sixth Circuit has explained, "Rule 12 was drafted by the Advisory Committee to prevent the dilatory motion practice fostered by common law procedure . . . a course of conduct that often was pursued for the sole purpose of delay." *Rauch v. Day & Night Mfg. Corp.*, 576 F.2d 697, 701 n.3 (6th Cir. 1978) (quoting 5C Wright & Miller, Federal Practice & Procedure § 1384 (3d ed.)). To prevent such sandbagging, "[Rule 12](g) contemplates the presentation of an omnibus pre-answer motion in which defendant advances every Rule 12 defense and objection he may have that is assertable by motion." *Id.* (quoting Wright & Miller § 1384). A defendant cannot assert its Rule 12 "defenses and objections in piecemeal fashion but must present them simultaneously." *Id.* (quoting Wright & Miller § 1384). That rule of consolidation and waiver applies to the defense of improper venue under Rule 12(b)(3). *See* Fed. R. Civ. P. 12(h)(1)(A).

In its first motion to dismiss, the government did not argue that venue was improper based on the germaneness requirement. Instead, the government's only venue argument was that venue

was improper because the Dayton Area Chamber had allegedly failed to identify a member with standing—an argument that the government has now abandoned. *See* Dkt. 33 at 2, 11, 15. Although the Sixth Circuit has not decided how Rule 12(g)(2) applies in the event of an amended pleading, the widespread consensus is that "[t]he filing of an amended complaint will not revive the right to present by motion defenses that were available but were not asserted" before the amendment. *Williamson v. Recovery Ltd. P'ship*, No. C2-06-292, 2009 WL 3172648, at *3 (S.D. Ohio Sept. 30, 2009) (quoting Wright & Miller § 1388); *Limbright & Hofmeister*, No. 5:09-CV-107, 2010 WL 1740905, at *2 (E.D. Ky. Apr. 27, 2010) (citing Wright & Miller § 1388); *see Burton v. Ghosh*, 961 F.3d 960, 966–67 (7th Cir. 2020); *Krinsk v. SunTrust Banks, Inc.*, 654 F.3d 1194, 1202–03 (11th Cir. 2011); *Rowley v. McMillan*, 502 F.2d 1326, 1332–33 (4th Cir. 1974).

The germaneness argument was undoubtedly "available" to the government, Fed. R. Civ. P. 12(g)(2), when it filed its first motion. The original complaint, which was filed more than six months before the government ever said a word about germaneness, contained the same allegations regarding venue and the Dayton Area Chamber's purpose as the amended complaint. *Compare* Dkt. 1 ¶¶ 26, 27 (original complaint) *with* FAC ¶¶ 27, 28 (amended complaint). Because Plaintiffs' venue allegations have not changed, neither may the government's venue defenses. *See Limbright*, 2010 WL 1740905, at *2; *Williamson*, 2009 WL 3172648, at *3.

That the government's first motion to dismiss raised *some* venue defense, *see* Dkt. 33 at 2, 15, does not mean it can raise a *different* one now. "The fact that both motions raise a defense based upon improper venue does not deactivate Rule 12(g) and Rule 12(h)(1). The policy concern underlying the consolidation requirement is violated whether the second motion raises a new Rule 12(b) defense or whether it raises a new theory supporting the original Rule 12(b) defense." *Randolph Eng'g Co. v. Fredenhagen Kommandit-Gesellschaft*, 476 F. Supp. 1355, 1358 (W.D. Pa.

1979); *see also Albany Ins. Co. v. Almacenadora Somex, S.A.*, 5 F.3d 907, 909–10 (5th Cir. 1993) (new theory of improper venue waived despite prior venue objection); *Tractor Supply Co. v. ACE Am. Ins. Co.*, No. 3:21-cv-00619, 2022 WL 4821988, at *3 (M.D. Tenn. Sept. 30, 2022) (similar).

The parties' joint scheduling motion, Dkt. 58, and this Court's order scheduling cross-motions for summary judgment, Dkt. 59, do not allow the government to circumvent Rule 12(g). *Cf. Williamson*, 2009 WL 3172648, at *3 (denying motion to dismiss as barred by Rule 12(g) because granting leave to resubmit motion does not give defendants a "second bite at the apple" (quotation marks omitted)). After Plaintiffs amended their complaint, the parties disputed whether to proceed directly to cross-motions for summary judgment (as Plaintiffs proposed) or first undergo another round of motion-to-dismiss briefing (as the government proposed). One of the government's arguments for filing another motion to dismiss was that "Defendants intend to move to dismiss for lack of venue, which may be waived if not included in a Rule 12 motion." Dkt. 58 at 8. The government did not describe its contemplated venue objection. In response, Plaintiffs acknowledged that the government would not waive its venue objections merely by failing to "include them in a document labeled 'motion to dismiss.'" *Id*. at 5–6. In other words, the form of the motion, if directed or approved by the Court, would not result in waiver. *Id*. At no point did Plaintiffs suggest that the government could disregard Rule 12(g)(2) and raise a new venue objection that would have been waived *under either party's* proposal—*i.e.*, irrespective of the form of motion.

Nor can the government argue that its new venue objection is non-waivable because its underlying objection to the Dayton Area Chamber's standing is a non-waivable issue of subject matter jurisdiction. Venue and subject matter jurisdiction are distinct doctrines governed by separate rules of forfeiture and waiver. "Venue, largely a matter of litigational convenience, is

waived if not timely raised. Subject-matter jurisdiction, on the other hand, concerns "a court's competence to adjudicate a particular category of cases" and "must be considered by the court on its own motion, even if no party raises an objection." *Wachovia Bank v. Schmidt*, 546 U.S. 303, 305 (2006); *see Tobias-Chaves v. Garland*, 999 F.3d 999, 1002 (6th Cir. 2021) ("[A] party can waive the issue of improper venue by failing to raise it in their first responsive pleading motion, but a party cannot waive the issue of subject matter jurisdiction"). And if the Dayton Area Chamber alone were dismissed for lack of standing, this suit could still proceed here because other Plaintiffs have standing. *See Biden v. Nebraska*, 600 U.S. 477, 489 (2023) ("If at least one plaintiff has standing, the suit may proceed"). As a result, the Court need not and should not consider the government's waived venue objection based on the germaneness requirement.

2. This Lawsuit Is Germane to the Purposes of the Dayton Area Chamber of Commerce.

In any event, the government's belated venue objection is meritless. "[T]he interests [that the Dayton Area Chamber] seeks to protect" in this suit "are germane to the organization's purpose." *Hunt*, 432 U.S. at 343 (quotation marks omitted).[1]

The germaneness requirement is "undemanding." *Nat'l Lime Ass'n*, 233 F.3d at 636 (quoting *Hodel*, 840 F.2d at 58); *see also Ass'n of Am. Physicians & Surgeons, Inc. v. Tex. Med. Bd.*, 627 F.3d 547, 550 n.2 (5th Cir. 2010) (same); *Presidio Golf Club v. Nat'l Park Serv.*, 155 F.3d 1153, 1159 (9th Cir. 1998) (same); *Schalamar Creek Mobile Homeowner's Ass'n v. Adler*, 855 F. App'x 546, 553 (11th Cir. 2021) (per curiam) (same). To satisfy this "modest" requirement, all that is necessary is "mere pertinence between litigation subject and organizational purpose." *Hodel*,

[1] As noted, the government does not dispute that the Dayton Area Chamber satisfies the first prong of the associational standing test (that "'its members, or any one of them,'" would "otherwise have standing to sue," *Hunt*, 432 U.S. at 342–43 (quoting *Warth*, 422 U.S. at 511)), and the government's argument under the third prong (whether this suit "requires the participation of individual members," *id.*) is in no way specific to the Dayton Area Chamber and is refuted above. *See* Gov't Br. 12.

840 F.2d at 58. A court need only "determine whether an association's lawsuit would, if successful, reasonably tend to further the general interests that individual members sought to vindicate in joining the association and whether the lawsuit bears a reasonable connection to the association's knowledge and experience." *Bldg. & Constr. Trades Council*, 448 F.3d at 149.

The Dayton Area Chamber easily satisfies that "low threshold." *Ass'n of Am. Physicians*, 627 F.3d at 550 n.2, because it was "organized for a purpose germane to the subject of [the] claim[s]" in this litigation, *United Food*, 517 U.S. at 555–56. The Dayton Area Chamber "strives to improve the region's business climate . . . through public policy advocacy." FAC ¶ 28. Contrary to the government's suggestion, the Dayton region is not an isolated island or backwater disconnected from the national economy, as if its residents and businesses were unaffected by sweeping new federal laws. Dayton is one of the largest cities in one of the most populous states in the Union—a state whose $820 billion GDP would make it the twentieth-largest economy in the world.[2] The Dayton metropolitan region is home to more than 800,000 residents[3] and thousands of businesses, including companies in the pharmaceutical and healthcare industry.[4]

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[2] *See* U.S. Bureau of Econ. Analysis, *Gross Domestic Product: All Industry Total in Ohio* (Sept. 29, 2023), https://fred.stlouisfed.org/series/OHNGSP; World Bank, *GDP (current US $)* (2024), https://data.worldbank.org/indicator/NY.GDP.MKTP.CD.

[3] U.S. Census Bureau, *Datasets: Annual Resident Population Estimates for Metropolitan and Micropolitan Statistical Areas and Their Geographic Components for the United States: April 1, 2020 to July 1, 2022* (May 2023), https://www.census.gov/data/tables/time-series/demo/popest/2020s-total-metro-and-micro-statistical-areas.html.

[4] *See, e.g.*, Dayton Dev. Coal., *Healthcare* (2024), https://www.daytonregion.com/dayton-region-economy/industries/healthcare ("The greater Dayton Region invites you to explore the vast business base that is the healthcare industry in Southwest Ohio. From bioscience to a global leadership in medical research, you can find it right here.") (including pages for companies in pharmaceutical and other health care sectors); Ohio Life Scis., *Life Sciences in Ohio's Six Regions* (2023), https://ohiolifesciences.org/ohio/ ("The life sciences industry's economic impact is felt throughout the state, with life sciences-related companies found in 83 of 88 Ohio counties, and all six Ohio regions have experienced growth while playing a role in advancing critical discoveries."); Adare Pharma. Sols., *Our Facilities* (2024), https://adarepharmasolutions.com/facilities/ (featuring 179,000 square-foot research center in Dayton suburb of Vandalia); Nat'l Resilience, Inc., *Resilience Announces Expansion in West Chester* (Dec. 11, 2023), https://resilience.com/news/resilience-announces-expansion-in-west-chester; Dayton Dev. Coal., *Global Pharmaceutical Company Expands Manufacturing Capabilities in Ohio* (2024), https://daytonregion.com/regional-business-development/success-stories/global-pharmaceutical-company-expands-manufacturing.

The Dayton Area Chamber is committed to "striv[ing] for a business friendly legislative and regulatory environment that encourages the growth and economic prosperity of businesses." Dkt. 29-2, Kershner Decl. at PageID 171 ¶¶ 5, 6. This litigation is obviously "pertinen[t]" to that purpose. *Hodel*, 840 F.2d at 58. As the president and CEO of the Dayton Area Chamber explained in a joint op-ed with the president and CEO of its co-Plaintiff the Ohio Chamber:

> If the government can establish price controls for essential medicines through an opaque regime without allowing for judicial review, it sets a dangerous precedent that could extend to other vital industries. . . . [T]he imposition of government price controls hampers innovation and jeopardizes free enterprise across business as a whole. This is why the Dayton Area Chamber of Commerce and the Ohio Chamber of Commerce have stood up against these detrimental measures to safeguard the principles of free enterprise and protect the future well-being of businesses in the Dayton area, the State of Ohio and the United States.

Chris Kershner & Steve Stivers, *Ohio Businesses Cannot Stand for Government Overreach*, Dayton Daily News (June 25, 2023), http://tinyurl.com/4fvkedsk. As Mr. Kershner further noted in a press release, "[t]he Dayton Area Chamber of Commerce has various members across the supply chain that are impacted by this federal law."[5] Because the Dayton Area Chamber's goals in this litigation are related to its purpose and achieving its goals will advance its members' interests, it "readily meets the germaneness requirement." *Ctr. for Sustainable Economy v. Jewell*, 779 F.3d 588, 597 (D.C. Cir. 2015).

The government's assertion that the Dayton Area Chamber's goals have no "connection to this lawsuit, which challenges federal legislation affecting a handful of pharmaceutical giants . . . none of which has any apparent connection to the Dayton area," Gov't Br. 13, is wrong on the facts and the law. First, as to the facts, the suggestion that the challenged IRA provisions affect only "a handful of pharmaceutical giants" is false. Apart from a narrow, "[t]emporary" price floor for some

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[5] Dayton Area Chamber of Com., *Dayton Area Chamber of Commerce Joins Ohio, Michigan and U.S. Chambers in Lawsuit Against Federal Government Overreach* (June 9, 2023), https://daytonchamber.org/dayton-area-chamber-of-commerce-joins-ohio-michigan-and-u-s-chambers-in-lawsuit-against-federal-government-overreach/.

of the very smallest manufacturers, *see* 42 U.S.C. § 1320f-3(b)(2)(F)(ii), the IRA provisions apply to every pharmaceutical manufacturer regardless of size, *see id.* § 1320f. Over the next several years, the number of products, and thus companies, subjected to "negotiation" will expand far beyond the government's asserted "handful," directly capturing more and more of the entire market. Among other effects on the industry as a whole, a price-control regime naturally harms investment in companies large and small because it reduces expected returns.[6] Not surprisingly, a recent survey of biotechnology companies found that companies of every size are "upending pipeline and business strategies" in response to the IRA; only 9% do not expect to be affected, and 34% (including small and medium-sized companies) are "bracing" for "major" or "existential" changes.[7] And that is not to mention the inevitable effects on other enterprises in the supply chain, such as suppliers of raw materials, distributors, equipment makers, and builders of laboratories; on participants in the broader healthcare system, all the way from healthcare providers to insurers to employers (many of whom self-insure); and, finally, on all companies harmed by the precedent set by the IRA provisions in establishing black-box government control over basic business decisions.

Second, as to the law, the government correctly acknowledges that "the germaneness requirement mandates pertinence between *litigation subject* and organizational purpose." Gov't Br. 12 (emphasis added) (quoting *Ctr. for Sustainable Economy*, 779 F.3d at 597). But then the government ignores this rule by focusing on the nexus between *members' injuries* and organizational purpose. *See Ctr. for Sustainable Economy*, 779 F.3d at 597 n.9 ("Germaneness

[6] *See, e.g.*, Stephen Rapundalo, *What Impact Is The Inflation Reduction Act Already Having On Biopharma Companies, And What More Can The Industry Do Going Forward?*, Life Sci. Leader (Sept. 1, 2023), https://www.lifescienceleader.com/doc/what-impact-is-the-inflation-reduction-act-already-having-on-biopharma-companies-and-what-more-can-the-industry-do-going-forward-0001 (noting that "[c]ompanies are expressing concerns over future revenue and are beginning to reduce investment in small molecule innovation" and that "[a]nalysts project a 3%-5% decline in market valuation, along with significant job losses").

[7] C. Simone Fishburn, *IRA Survey: Biotechs Bracing for Impact*, Biocentury (Mar. 16, 2023), https://www.biocentury.com/article/647205/ira-survey-biotechs-bracing-for-impact.

requires 'pertinence between litigation subject and organizational purpose' *not, as the dissent contends, germaneness of members' injuries to organizational purpose. The difference is a significant one*." (emphasis added)). The subject of this litigation—a challenge to government overreach that threatens to hamper economic prosperity and create an unfavorable environment for business, including in the Dayton area—is plainly relevant to the Dayton Area Chamber's goal of promoting a pro-business environment in the Dayton region. That connection is all that is required. *See Neighborhood Action Coal. v. City of Canton*, 882 F.2d 1012, 1017 (6th Cir. 1989) (finding associational standing where "the interests [the association] seeks to protect in this lawsuit are germane to its purpose"); *see also In re Cincinnati Policing*, 209 F.R.D. 395, 398 (S.D. Ohio 2002) (explaining that organizations had associational standing because the "interests at stake" were germane to the organizations' purposes).

The government makes a similar mistake when it suggests that "there is no 'guarantee[] that the grievances expressed in' this lawsuit 'apply to a critical mass of association members.'" Gov't Br. 14 (quoting *Hodel*, 840 F.2d at 58 n.21). There is no requirement that a "'critical mass'" of members have a "cognizable" Article III injury, *id.* (quoting *Hodel*, 840 F.2d at 58 n.21); otherwise, the second prong of the associational standing test would swallow the first, which requires only *one* member with standing. The D.C. Circuit did not hold otherwise in *Hodel*. *See Am. Med. Ass'n v. United HealthCare Corp.*, No. 00 CIV. 2800 (LMM), 2007 WL 1771498, at *20 (S.D.N.Y. June 18, 2007) ("The *Hodel* Court neither adopts nor applies the 'critical mass' language in its analysis of whether the germaneness requirement is satisfied."). The sentence the government quotes regarding a "critical mass," which was dicta in a footnote, referred to the germaneness requirement's role in helping to ensure that a suit is not so far removed from the concerns of the association's membership as to create a "wholesale mismatch between litigation topics and

organizational expertise." *Hodel*, 840 F.2d at 57. There is no such mismatch here. And to Plaintiffs' knowledge, "no federal court has applied the 'critical mass' test here urged by Defendants," *Am. Med. Ass'n*, 2007 WL 1771498, at *20, to deny an organization the opportunity to litigate on behalf of its affected members where such litigation is indeed relevant to its organizational purpose.

Finally, the cases that the government characterizes as applying a "lens of geographic specificity" to germaneness, Gov't Br. 14, do nothing of the sort. In each of the cited decisions, the court held that an association organized to pursue its members' interests in a particular area had standing to challenge actions that were limited to that same area. *See Pennell v. City of San Jose*, 485 U.S. 1, 4, 7 n.3 (1988) (in challenge to local rent-control ordinance, group "organized for the purpose of representing the interests of the owners and lessors of real property in San Jose in this lawsuit" had standing (quotation marks omitted)); *Neighborhood Action Coal.*, 882 F.2d at 1016, 1017 (in litigation regarding municipal services in Canton, association with "purpose of fostering open housing in the City of Canton" had standing); *In re Cincinnati Policing*, 209 F.R.D. at 398 (association "founded to combat racial subordination in Hamilton County" had standing to challenge policing practices in Cincinnati). Not one of these decisions suggests that an organization whose purpose is to improve its region's business climate cannot challenge actions that concededly affect businesses "around the globe," Gov't Br. 13. The government's suggestion that the Dayton Area Chamber should not concern itself with major federal legislation that upends a critical industry, with impacts in Dayton and everywhere else in the United States, is both legally baseless and offensive to the Dayton Area Chamber and its members.

3. Dismissal for Lack of Venue Would Be Improper in All Events.

Even if this Court were to reach the government's waived venue objection and to find that the Dayton Area Chamber cannot support venue, the proper remedy would be transfer to the Eastern Division of this District, not dismissal. When venue is found to be improper, the court

"shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought." 28 U.S.C. § 1406(a). Venue in this District is not predicated solely on the Dayton Area Chamber; another Plaintiff—the Ohio Chamber of Commerce—also resides in this District. *See* FAC ¶ 29; Gov't Br. 15 n.4; 28 U.S.C. § 1391(e)(1) (venue proper "in any judicial district" in which plaintiff resides). The purpose of section 1406(a) is to "remov[e] whatever obstacles may impede an expeditious and orderly adjudication of cases and controversies on their merits." *Goldlawr, Inc. v. Heiman*, 369 U.S. 463, 466–67 (1962), *superseded by statute on other grounds as recognized by Franco v. Mabe Trucking Co.*, 3 F.4th 788, 793–94 (5th Cir. 2021). Especially given the belated nature of the government's objection, dismissing this action would be inconsistent with the purpose of section 1406(a).

C. The Court Has Subject-Matter Jurisdiction Over Plaintiffs' Claims Challenging the IRA's "Excise Tax."

The government's final two procedural arguments are directed only to counts 3 and 4 of the amended complaint, which challenge the constitutionality of the IRA's so-called "excise tax," and are equally unavailing. The government contends, first, that Plaintiffs lack standing to assert these claims because only non-parties—the Treasury Department and the IRS—are responsible for assessing and collecting the "excise tax" and so relief against Defendants HHS and CMS would not redress Plaintiffs' injuries. Gov't Br. 21–24. The government's assumption that HHS and CMS have nothing to do with enforcing the "excise tax" is flatly contradicted by the IRA and by CMS's own guidance. Because Plaintiffs sued HHS and CMS and those agencies play an important role in the administration of the "excise tax," Plaintiffs' requested relief is more than "likely" to redress their injuries. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 38 (1976)). Second, the government seeks to avoid a decision on the

merits of Plaintiffs' challenges to the "excise tax" by invoking the Anti-Injunction Act, but the AIA does not and cannot bar Plaintiffs' constitutional claims.

1. Plaintiffs' claims challenging the "excise tax" are redressable in this suit.

To establish standing, a plaintiff must show that "it is likely, rather than merely speculative, that a favorable decision could redress the injury." *Miller v. City of Wickliffe*, 852 F.3d 497, 503 (6th Cir. 2017) (citing *Defs. of Wildlife*, 504 U.S. at 561). "Plaintiffs suing public officials can satisfy the causation and redressability requirements of standing by demonstrating a meaningful nexus between the defendant and the asserted injury." *Durham v. Martin*, 905 F.3d 432, 434 (6th Cir. 2018) (quoting *Kitchen v. Herbert*, 755 F.3d 1193, 1201 (10th Cir. 2014)). Where multiple sets of officials coordinate to administer a statute, it is generally sufficient to sue an official who "ha[s] a meaningful role in the statute's enforcement." *Lavin v. Husted*, 689 F.3d 543, 546 (6th Cir. 2012).

Here, it is very likely, and indeed certain, that a favorable decision would redress Plaintiffs' injuries from the threatened enforcement of the "excise tax." Plaintiffs' amended complaint asks this Court to "[e]njoin HHS from implementing the IRA's drug price control program," FAC ¶ 266, "[e]njoin HHS from enforcing the IRA's 'excise tax,'" *id.* ¶ 267, "[d]eclare that the IRA's 'excise tax' violates the Excessive Fines Clause," *id.* ¶ 262, and "[d]eclare that the IRA's 'excise tax' exceeds Congress's enumerated powers," *id.* ¶ 263. HHS (including its sub-agency CMS) clearly has a "'meaningful nexus'" to the enforcement of the "excise tax," *Durham*, 905 F.3d at 434 (quoting *Kitchen*, 755 F.3d at 1201), because HHS is responsible for the statutory and regulatory machinery that leads to its imposition.

Pursuant to 42 U.S.C. § 1320f(a), HHS is tasked with "establish[ing] a Drug Price Negotiation Program" and, among other responsibilities, "carry[ing] out the publication and administrative duties and compliance monitoring in accordance with sections 1320f-4 and 1320f-

5." Under § 1320f-5(a)(6), HHS's "administrative duties" include "[t]he sharing with the Secretary of the Treasury of such information *as is necessary to determine the tax imposed by section 5000D of the Internal Revenue Code of 1986, including the application of such tax to a manufacturer*, producer, or importer *or the determination of any date described in section 5000D(c)(1)* of such Code" (emphasis added). And 26 U.S.C. § 5000D itself plainly reflects the necessity of coordination between HHS and the IRS. For example, the "excise tax" is triggered only during specified "noncompliance periods," which depend on "determination[s]" or certifications made by "the Secretary of Health and Human Services." 26 U.S.C. § 5000D(b). In sum, HHS and CMS are indispensable to the administration of the IRA's "excise tax."

CMS's own guidance further confirms its "meaningful role" in enforcing the "tax." *Lavin*, 689 F.3d at 546. For example, in setting forth the implementation timeline for initial price applicability year 2026, CMS's guidance specifies that if manufacturers do not enter into an "agreement" with CMS by October 1, 2023, they will be "referred to IRS." CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 at 91 (June 30, 2023) ("Revised Guidance"). Similarly, the guidance states that at the end of the "negotiation" period, "[m]anufacturers of selected drugs without an MFP in place are referred to IRS." *Id.* at 91–92. CMS also notes that it "will closely monitor the Primary Manufacturer's compliance with the terms of the Agreement and other aspects of the Negotiation Program." *Id.* at 167. As part of that compliance role, CMS "will issue reminder letters prior to manufacturer deadlines with warnings of potential applicability of excise taxes," send "written requests for corrective action when applicable," and issue "written notification that a Primary Manufacturer may be subject to enforcement action as applicable." *Id.* CMS warns that failure "to comply with certain Negotiation

Program deadlines and other requirements of the Negotiation Program may result in potential excise tax liability." *Id.*

The government's brief ignores all of that. Contrary to the government's suggestion, the fact that the "excise tax" itself is "codified in the Internal Revenue Code" does not mean that it is hermetically sealed off from HHS. Gov't Br. 22. HHS's information-sharing, compliance monitoring, and referral responsibilities are necessary precursors to the application of the "tax." Such actions "assist in giving effect to the law." *Kitchen*, 755 F.3d at 1204 (quoting *Prairie Band Potawatomi Nation v. Wagnon*, 476 F.3d 818, 828 (10th Cir. 2007)). The IRS may pull the final trigger, but "[HHS]'s actions are unquestionably a link in the chain of causation and redressability." *Sierra Club v. EPA*, 60 F.4th 1008, 1018–19 (6th Cir. 2023); *see also Constitution Party v. Aichele,* 757 F.3d 347, 366–68 (3d Cir. 2014) ("[T]here is room for concurrent causation").

The Sixth Circuit's decision in *Lavin*—which the government also ignores—makes clear that the IRS's role in assessing or collecting the "excise tax" does not exclude a "meaningful role" in enforcement for HHS. 689 F.3d at 546; Gov't Br. 22–23. In *Lavin*, the defendants argued that "the plaintiffs have chosen the wrong defendant" because only state prosecutors, not the Secretary of State, could "bring criminal charges for violations" of the relevant statute. 689 F.3d at 546. But the Secretary still had a "meaningful role in the statute's enforcement" because he had the duty to "investigate" and "report violations" for prosecution. *Id.* (quotation marks omitted). Because enjoining the Secretary would bring the plaintiffs "meaningful if not total relief," the Sixth Circuit held, "[t]he Secretary's redressability argument [was] without merit." *Id.* So too here.

The government invokes *Haaland v. Brackeen,* 599 U.S. 255 (2023), *see* Gov't Br. 23–24, but this case bears no resemblance to the circumstances in that case. In *Brackeen*, the plaintiffs did "not dispute" that the statute was enforced only by *state* courts and agencies, but the plaintiffs

sought injunctive and declaratory relief only against *federal* parties (who had no role in enforcement), on the theory that "state courts are likely to defer to a federal court's interpretation of federal law." 599 U.S. at 293–94. The Court rejected that theory of redressability because "[r]edressability requires that the court be able to afford relief *through the exercise of its power*, not through the persuasive or even awe-inspiring effect of the opinion *explaining* the exercise of its power." *Id.* (quotation marks omitted). Here, as Plaintiffs have explained, HHS and CMS have a meaningful and necessary role in enforcing the "excise tax." And Plaintiffs are not seeking a mere "advisory opinion." Gov't Br. 23 (quoting *Brackeen*, 599 U.S. at 293). Rather, they are calling on this Court to "exercise . . . its power" to award appropriate injunctive and declaratory relief against "officials who matter." *Brackeen*, 599 U.S. at 293–94 (quotation marks omitted).

2. The Anti-Injunction Act does not bar adjudication of Plaintiffs' claims.

As Plaintiffs anticipated (*see* Dkt. 64 ("Pl. Br.") at 39–41), the government also seeks to avoid the merits of Plaintiffs' constitutional challenges to the "excise tax" by invoking the Anti-Injunction Act. Gov't Br. 24–31.[8] The AIA generally bars suits filed "for the purpose of restraining the assessment or collection of any tax." 26 U.S.C. § 7421. Under the AIA, taxes can "*ordinarily* be challenged only after they are paid, by suing for a refund." *NFIB*, 567 U.S. at 543 (emphasis added). But the IRA's "excise tax" is no ordinary "tax." It does not fall within the purview of the AIA to begin with, and even if it did, it is precisely the sort of extraordinary measure—so draconian as to foreclose the possibility of a post-deprivation refund suit—that calls for application of the AIA's equitable exceptions. Any other approach would put the AIA itself on a collision course with the Constitution. *See Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 681 n.12 (1986)

[8] For good reason, the government does not suggest that the AIA bars any of Plaintiffs' other claims (counts 1, 2, and 5). *See CIC Servs., LLC v. IRS*, 593 U.S. 209, 219 (2021) ("[W]e reject the Government's argument that an injunction against [a requirement backed by a tax penalty] is the same as one against the tax penalty").

(recognizing the "serious" constitutional questions that would arise if a statute were construed to deny a judicial forum for constitutional claims (quoting *Weinberger v. Salfi*, 422 U.S. 749, 762 (1975))); *Wills v. HHS*, 802 F.2d 870, 873 (6th Cir. 1986) (noting "the strong presumption in favor of the availability of judicial review when constitutional issues are presented").

As an initial matter, this suit would be a peculiar case for the application of the AIA because, as the Supreme Court and the Sixth Circuit have observed, the AIA exists to "protect[] the Government's ability to collect a consistent stream of revenue." *Jarrett v. United States,* 79 F.4th 675, 683 (6th Cir. 2023) (quoting *NFIB*, 567 U.S. at 543); *see Z St. v. Koskinen*, 791 F.3d 24, 30 (D.C. Cir. 2015) ("[T]he Act does not apply in situations where . . . the claim has no implication[s] for tax assessment or collection" (quotation marks omitted)); Erin M. Hawley*, The Equitable Anti-Injunction Act*, 90 Notre Dame L. Rev. 81, 124 (2014). The IRA's "excise tax" of up to 1,900% is so exorbitant that, as the non-partisan experts at the Congressional Budget Office and the Joint Committee on Taxation confirmed, it will not raise any revenue in the first place. *See* CBO, Estimated Budgetary Effects of Public Law 117-169, to Provide for Reconciliation Pursuant to Title II of S. Con. Res. 14, at 5 (Sept. 7, 2022), https://www.cbo.gov/system/files/2022-09/PL117-169_9-7-22.pdf; Jt. Comm. on Tax'n, No. JCX-46-21, Estimated Budget Effects of the Revenue Provisions of Title XIII, at 8 (Nov. 19, 2021), https://bit.ly/3plC4cd. The government's cited cases involve taxes that "f[a]ll squarely into the parameters" of ordinary taxation, *see* Gov't Br. 27, and therefore provide "little guidance" here. *Norcal Tea Party Patriots v. IRS*, No. 1:13-CV-341, 2014 WL 3547369, at *10 (S.D. Ohio July 17, 2014).

Perhaps recognizing that a 1,900% "excise tax" is indefensible, the government tries to spin the rate as "only" 95% because "the maximum ratio of the tax to the total amount the manufacturer charges" (*i.e.*, *including* the tax) "is 95%." Gov't Br. 8. That is pure sophistry. What

matters to the manufacturer is the ratio of the "tax" to the amount the manufacturer *receives* (*i.e.*, its revenue *excluding* the tax, since the tax goes to the government). Here, for every dollar the manufacturer receives on the sale of the drug when the "excise tax" is at its highest level, the government collects $19. That is a penalty of 19 times revenue (*i.e.*, 1,900%). The government's own example demonstrates as much. *See id.* ("$95 is allocated to the § 5000D tax and $5 is allocated to the price of the designated drug"). And the IRS guidance confirms the same calculus. *See* IRS Notice No. 2023-52, 2023-35 I.R.B. 650, at 2–4 (Aug. 4, 2023).

The government is conflating the tax-*inclusive* rate (what the IRA calls the "applicable percentage," *see* 26 U.S.C. § 5000D(a)) with the tax-*exclusive* rate (the typical way to represent a sales tax) in order to make the "excise tax" seem less draconian than it is. *See* Tax Policy Ctr., *Tax Policy Center Briefing Book: What Is the Difference Between a Tax-Exclusive and Tax-Inclusive Sales Tax Rate?* (May 2020), http://tinyurl.com/32ejney2 ("Sales tax rates are typically quoted in tax-*exclusive* terms" (emphasis added)); David Shakow & Reed Shuldiner, *A Comprehensive Wealth Tax*, 53 Tax L. Rev. 499, 514 n.31 (2000) ("Sales taxes generally are stated on a tax-exclusive basis (the tax base excludes the funds used to pay the tax)"). That convention likely explains why, when the Congressional Research Service analyzed the "excise tax," it reported that "[t]he excise tax rate would range from 185.71% to 1,900% of the selected drug's price depending on the duration of noncompliance." Cong. Rsch Serv., No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376) at 4 (Aug. 10, 2022), https://crsreports.congress.gov/product/pdf/R/R47202; *see* FAC ¶¶ 117–19 (reproducing CRS calculations). As former CBO director Douglas Holtz-Eakin and other commentators have explained: "the 95 percent rate on the tax-inclusive price *translates to a 1,900 percent rate on the*

price received by the firm."[9] Obviously, no manufacturer could afford to bear that kind of burden. *See* Dkt. 29-5, Staff Decl. at PageID 191 ¶ 16. That is why the CBO and the Joint Committee on Taxation both projected that the "excise tax" would raise no revenue.

Moreover, as the government acknowledges, the AIA is subject to two well-established exceptions. Gov't Br. 27–30. This case meets both. First, the *Williams Packing* exception applies because Plaintiffs would suffer "irreparable injury" if not permitted to challenge the crushing "excise tax" and "'it is clear that under no circumstances could the Government ultimately prevail'" on the merits. *Bob Jones Univ. v. Simon*, 416 U.S. 725, 737 (1974) (quoting *Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1, 7 (1962)). The government does not appear to dispute that, if a manufacturer were required to pay a penalty of 19 times the price of its product on all sales (or even all Medicare sales), it would suffer irreparable harm. Instead, the government tries to sidestep the issue by suggesting that the IRA's "excise tax" could be treated as "divisible"—*i.e.*, subject to deferral after a single taxed transaction. *See* Gov't Br. 28–29.[10]

That purported solution is a mirage. To begin with, it is based entirely on non-binding IRS guidance and is far from a guarantee the taxpayer can rely on. Citing an IRS policy statement, the government says that "while a refund suit is pending," the IRS "typically" does not collect the balance of a divisible tax and will instead "'exercise forbearance'" "except when unusual circumstances warrant." Gov't Br. 28 (quoting IRS Policy Statement 5-16, IRM 1.2.1.6.4(6)). But

[9] Gordon Gray, Douglas Holtz-Eakin, & Kenneth Thorpe, *The Medicare Budget Implications of the Inflation Reduction Act* (Oct. 3, 2023), http://tinyurl.com/3h5vp8m3 (emphasis added); *see also, e.g.*, Fed. Tax Coordinator ¶ W-6603 (2d ed.) (noting that "the 95% tax-inclusive rate is equal to a 1,900% tax-exclusive rate" and that "[b]ecause these rates are so steep, drug manufacturers are expected to comply with the negotiation requirements to avoid paying the tax" and "the Joint Committee on Taxation staff has estimated that the excise tax will have no effect on federal budget receipts").

[10] Citing non-binding IRS guidance, the government also maintains that the IRA's "excise tax" applies only to Medicare sales, rather than to all U.S. sales of selected drugs. Gov't Br. 8 (citing IRS Notice No. 2023-52); *accord id.* at 73 n.23. But the statute refers to "sales" in general, not a subset of sales. 26 U.S.C. § 5000D(b)(1)–(4). And even if the "excise tax" applied only to Medicare sales, that would not change its punitive nature or its devastating impact.

even assuming that a manufacturer were prepared to stake its survival on the prospect that the IRS will "exercise forbearance" regarding the amounts it insists on immediately *collecting*, the manufacturer would rack up unsustainable "excise tax" liability if it sold its drug beyond the one taxable transaction envisioned by the government. And the manufacturer could not simply stop selling its drugs after a single transaction. Apart from the unworkability of running a production line to make a single unit, that would deprive millions of patients of vitally needed treatments and cause irreparable harm to the manufacturer's goodwill. *See Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp*., 511 F.3d 535, 550 (6th Cir. 2007) ("The loss of customer goodwill often amounts to irreparable injury because the damages flowing from such losses are difficult to compute" (quoting *Basicomputer Corp. v. Scott*, 973 F.2d 507, 512 (6th Cir. 1992))); Dkt. 29-5, Staff Decl. at PageID 191–92 ¶¶ 16–18; Dkt. 29-2, Kershner Decl. at PageID 173–74 ¶¶ 12–13. The government's "divisible tax" argument is therefore just an illusion—an attempt to make the "excise tax" appear less onerous while doing nothing to mitigate its "unbearable" impact. Dkt. 29-5, Staff Decl. at PageID 191 ¶ 16. Unlike in *Bob Jones*, no manufacturer has a "full, albeit delayed opportunity to litigate" its constitutional challenges to the excise tax; there is effectively "no access at all to judicial review" of the constitutionality of the "excise tax" if the AIA is construed to bar Plaintiffs' claims. 416 U.S. at 746.[11]

As for the other *Williams Packing* requirement, it is "clear" that Plaintiffs will succeed on the merits. *Id.* at 737 (quoting 370 U.S. at 7). A penalty of up to 1,900% for the "offense" of refusing to "agree" to provide access to a valuable product at whatever price the government

[11] The government's claim that this Court "has already ruled that Plaintiffs are not likely to suffer irreparable injury absent immediate judicial relief" is misleading. Gov't Br. 28. The Court indicated that it was "not convinced" "[a]t this point" that Plaintiffs had shown irreparable harm at the preliminary injunction stage, *Chamber I*, 2023 WL 6378423, at *13—before Plaintiffs amended their complaint and submitted a supplemental declaration further setting forth the unrecoverable economic costs and other irreparable injuries to their members. *See* FAC ¶¶ 36–60; Dkt. 50-1, Staff Supp. Decl. at PageID 427–32 ¶¶ 4–32.

unilaterally chooses is so wildly disproportionate that the government has no prospect of prevailing on the merits of Plaintiffs' Excessive Fines Clause challenge. *See infra* Section V; Pl. Br. 36–44.

Plaintiffs likewise satisfy the equitable exception in *South Carolina v. Regan* because they lack "an alternative legal way to challenge the validity of [the] tax." 465 U.S. 367, 373 (1984). In an ordinary case, the "availability of a refund suit" precludes application of the *Regan* exception because taxpayers can pay the tax first and obtain full compensation later. *Id.* at 375–76. But for the *Regan* exception to have any meaning, the party must have "more than a mere possibility" of obtaining judicial review through a refund suit. *RYO Mach., LLC v. U.S. Dep't of Treasury*, 696 F.3d 467, 472 (6th Cir. 2012); *see Regan*, 465 U.S. at 381 (emphasizing "risk that the Anti-Injunction Act would entirely deprive the [plaintiff] of any opportunity to obtain review of its claims"); *In re Westmoreland Coal Co*., 968 F.3d 526, 536 (5th Cir. 2020) (describing *Regan* as requiring "an adequate, alternative remedy" (quoting *Interfirst Bank Dallas, N.A. v. United States*, 769 F.2d 299, 307 n.13 (5th Cir. 1985))). Otherwise, if the sole question were whether a refund suit were "legally available" in a purely formal sense, the government could condition a refund suit on the payment of a $100 million filing fee. Gov't Br. 30. Indeed, the government does not appear to dispute that the *Regan* exception applies where pursuing a refund suit is practically *impossible*; instead, the government's argument against the *Regan* exception is based on the misguided assumption that a refund suit here is merely "practically *challenging*" because manufacturers supposedly have the option of paying the "excise tax" up front thanks to its "divisible nature." *Id.* at 30 (emphasis added). As discussed above, however, any potential "divisibility" of the "excise tax" is irrelevant to its crushing burden. Even if a manufacturer only had to *pay* the IRS one sale's worth of "excise tax" up front, the manufacturer would incur untold liability on other sales while a refund suit was pending. No manufacturer could afford to run the

risk of owing billions of dollars. The obvious impact of the "excise tax" on its face (as confirmed by the CBO and the Joint Committee on Taxation), and the unrebutted evidence in this case, show that incurring the "excise tax" in order to challenge it in a refund action is not merely "challenging" but "literally unbearable." Dkt. 29-5, Staff Decl. at PageID 191 ¶ 16.[12]

The government is wise not to argue that the AIA applies even when it renders judicial review of constitutional claims practically impossible. That extreme position would make the AIA itself unconstitutional as applied to this case. *See Webster v. Doe,* 486 U.S. 592, 603 (1988) (noting the "'serious constitutional question' that would arise if a federal statute were construed to deny any judicial forum for a colorable constitutional claim" (quoting *Bowen*, 476 U.S. at 681 n.12)). "[A] statutory provision precluding *all* judicial review of constitutional issues removes from the courts an essential judicial function under our implied constitutional mandate of separation of powers, and deprives an individual of an independent forum for the adjudication of a claim of constitutional right." *Bartlett v. Bowen*, 816 F.2d 695, 703 (D.C. Cir.), *opinion reinstated on reconsideration sub nom. Bartlett ex rel. Neuman v. Bowen*, 824 F.2d 1240 (D.C. Cir. 1987) (per curiam). There is "little doubt that such a limitation on the jurisdiction of *both* state and federal courts to review the constitutionality of federal legislation . . . would be [an] unconstitutional infringement of due process." *Id.* (quotation marks omitted). Congress did not intend, and could not constitutionally have intended, the AIA to preclude all judicial consideration of meritorious constitutional challenges to anything that Congress labels a "tax." Rather than bring the AIA into constitutional doubt, the Court should apply the recognized equitable exceptions to the AIA and uphold Plaintiffs' constitutional challenges to the "excise tax."

[12] For the same reasons, the Declaratory Judgment Act, which is "coterminous" with the AIA and thus subject to the same exceptions, does not bar Plaintiffs' requested declaratory relief. *Z St.*, 791 F.3d at 26 (quoting *Cohen v. United States*, 650 F.3d 717, 727 (D.C. Cir. 2011)); *see Ecclesiastical Ord. of ISM of AM, Inc. v. IRS,* 725 F.2d 398, 402 (6th Cir. 1984).

II. The IRA's Price-Control Program Violates the Separation of Powers.

That the government is so eager to avoid the merits of Plaintiffs' constitutional challenges is no surprise. Among other fundamental defects, the unprecedented and unaccountable structure of the IRA's price-control program violates the separation of powers under both binding precedent and the original understanding of the Constitution. The government tries to defend Congress's delegation of vast, unreviewable power to HHS by pointing to a laundry list of cases upholding delegations, but those cases only confirm Plaintiffs' point: that when Congress establishes an administrative price-control regime, it must provide checks and balances such as a statutory standard of "just and reasonable" prices and judicial review. The government does not identify a single case upholding an administrative price-control regime that, like the IRA, lacks those crucial guardrails. The government also attempts to downplay the IRA's lack of constraints on HHS's decisionmaking. But the plain text of the IRA reveals that Congress gave HHS "virtually unfettered" discretion to upend the $600 billion pharmaceutical industry. *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 542 (1935). That boundless delegation, unchecked by internal or external procedural safeguards, lacks an "intelligible principle" to limit HHS and runs afoul of broader separation-of-powers principles by insulating both HHS and Congress from vital mechanisms of accountability.

1. As an initial matter, and contrary to the government's suggestion that Plaintiffs are relying solely on a "gloss on 'the original understanding'" rather than "binding" precedent, Gov't Br. 32, Plaintiffs' position is that the IRA's unconstitutional delegation is inconsistent with *both* precedent *and* the original understanding of the Constitution. *See* Pl. Br. 48–56. Plaintiffs' argument about the importance of looking beyond "isolated statutory phrases" and taking into account procedural "checks and balances" was based entirely on twentieth and twenty-first century precedents, including Sixth Circuit cases decided *last year*. *See id.* at 48–53. And in any event, as

then-Judge Kavanaugh observed in an analysis subsequently adopted by the Supreme Court, "lower courts should resolve questions about the scope of those precedents in light of and in the direction of the constitutional text and constitutional history." *Id.* at 53–54 (quotation marks omitted). Notably, the government does not dispute that the IRA's delegation to HHS would *fail* under the original understanding of the nondelegation doctrine because HHS can neither be described as merely "'fill[ing] up the details'" of a statutory scheme nor engaging in "modest fact-finding to ascertain 'particular contingencies.'" Pl. Br. 54–56 (quoting *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 42–43 (1825), and *Miller v. City of New York*, 109 U.S. 385, 393–94 (1883)). Thus, any ambiguities in Supreme Court or Sixth Circuit precedent should be construed against the government, as its position is inconsistent with the original understanding of the Constitution.

In any event, even without that construction, none of the government's cited precedents justifies the IRA's sweeping delegation of unbounded, unreviewable power. *See* Gov't Br. 32–34. Indeed, only two of the government's nondelegation cases involved administrative price-control regimes, and both cases illustrate the importance of minimum standards of fairness and opportunities for judicial review to constrain agency discretion and protect private rights. For example, in *Federal Power Commission v. Hope Natural Gas. Co.*, Congress required rates to be "just and reasonable" and permitted rate orders to be "challenged in the courts" for compliance with that standard. 320 U.S. 591, 602 (1944). Even the wartime emergency price controls in *Yakus v. United States*, a high-water mark for delegation, included more guardrails than the IRA. 321 U.S. 414 (1944). The Emergency Price Control Act not only required commodity prices to be "fair and equitable," but also provided that, "so far as practicable," the Price Administrator "shall ascertain and give due consideration to the prices prevailing between October 1 and October 15, 1941." *Id.* at 420–21 (quotation marks omitted). The Court thus held that the legal standards were

"sufficiently definite and precise to enable Congress, *the courts* and the public to ascertain whether the Administrator, in fixing the designated prices, has conformed to those standards." *Id.* at 426 (emphasis added). That the IRA lacks similarly precise standards, or even a general requirement of fairness, *see* Pl. Br. 10–13, is especially notable because wartime emergency delegations like the one in *Yakus* are typically given a wide berth. *See Panama Refining Co. v. Ryan*, 293 U.S. 388, 422 (1935) (noting that wartime delegations usually involve "an authority which was cognate to the conduct by [the President] of the foreign relations of the government"); *Lichter v. United States*, 334 U.S. 742, 754, 784–86 (1948) (justifying wartime delegation to recover "excessive profits" as "an attempt to determine a fair return on war contracts" and an exercise of "war powers" "for the sake of the defense of the nation when its survival is at stake").

Thus, the government's cases confirm that until the IRA, whenever Congress had delegated power to an agency to set prices, it had always moderated that power with checks and balances such as minimum standards of fairness, notice-and-comment rulemaking or other formal hearings, and judicial oversight. *See* Pl. Br. 57–58. In fact, the "intelligible principle" test originated in a case in which the Court recognized that agencies could exercise delegated power to set prices only "after hearing evidence and argument concerning them from interested parties*, all in accord with a general rule that Congress first lays down that rates shall be just and reasonable.*" *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 408–09 (1928) (emphasis added). Contrary to the government's suggestion that "Congress simply cannot do its job" here without a standardless, unreviewable delegation of power to HHS, Gov't Br. 34 (quoting *Consumers' Rsch. v. FCC*, 67 U.S. 773, 787 (6th Cir. 2023)), Congress has *always* provided specific legal standards, opportunities for judicial review, and other procedural safeguards to constrain agency price-setting. Congress has no excuse for failing to do so in the IRA.

As for the government's other cases, which do not involve price-control regimes, all of them included *some* statutory standard to constrain agency abuses, and *none* of them foreclosed judicial review. The government also ignores other relevant distinctions that mitigated the scope of those delegations. For example, the government touts a delegation to the FCC to regulate radio broadcast licensing as required by "public interest, convenience, or necessity." *Nat'l Broad. Co. v. United States*, 319 U.S. 190, 225–26 (1943) (quotation marks omitted). But the Court held that, in context, it was clear that this standard referred to "the interest of the listening public in 'the larger and more effective use of radio.'" *Id.* at 216 (quoting 47 U.S.C. § 303(g)); *see also id.* at 226 ("It is a mistaken assumption that this is a mere general reference to public welfare without any standard to guide determinations" (quotation marks omitted)). The Court also noted that the regulations were promulgated only after robust notice-and-comment rulemaking featuring testimony by "96 witnesses" over "73 days" of hearings. *Id.* at 195. And the rules were subject to judicial review to ensure that they were "based upon findings supported by evidence." *Id.* at 224. Similarly, the government repeatedly cites *American Power & Light Co. v. SEC* as an exemplar of "intelligible principle" analysis, *see* Gov't Br. 32–33, but omits the Court's emphasis on the availability of judicial review: "Private rights are protected by access to the courts to test the application of the policy in the light of these legislative declarations." 329 U.S. 90, 105 (1946); *see also id.* at 106 ("The legislative policies and standards being clear, judicial review of the remedies adopted by the Commission safeguards against statutory or constitutional excesses.").

Perhaps recognizing that the IRA's nondelegation problem is exacerbated by its sweeping prohibition on judicial review, *see* 42 U.S.C. § 1320f-7, the government denies that there is any "logical connection" between judicial review and nondelegation principles. Gov't Br. 36–38. But the Supreme Court, the Sixth Circuit, and other courts have recognized that "connection" time and

again—including, as noted above, in cases the government highlights. *See, e.g.*, *Am. Power & Light*, 329 U.S. at 105–06 (emphasizing "access to the courts to test the application" of statutory standards and guard "against statutory or constitutional excesses"); *Yakus*, 321 U.S. at 426 ("The standards . . . are sufficiently definite and precise to enable Congress, *the courts* and the public to ascertain whether the Administrator, in fixing the designated prices, has conformed to those standards" (emphasis added)); *Touby v. United States*, 500 U.S. 160, 168–69 (1991) (considering whether judicial review provisions of statute were "sufficient to permit a court to ascertain whether the will of Congress has been obeyed" (quotation marks omitted)); *Schechter*, 295 U.S. at 533, 541–42 (noting lack of "administrative procedure[s]" such as "judicial review to give assurance that the action of the [delegee] is taken within its statutory authority"); *see also United States v. Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) (collecting cases) (citing "[j]udicial review" and "notice and comment" rulemaking as relevant factors in evaluating a nondelegation challenge). The Sixth Circuit reaffirmed that connection just last year, when it explained that a delegation is permissible only "so long as Congress provides an administrative agency with standards guiding its actions *such that a court could ascertain whether the will of Congress has been obeyed*." *Consumers' Rsch.*, 67 F.4th at 787 (quoting *Skinner v. Mid-Am. Pipeline Co.*, 490 U.S. 212, 218 (1989) (emphasis added)). The "logical connection" between judicial review and nondelegation is thus not only "obvious," Gov't Br. 36; it is established by binding precedent.

The government cites no authority to the contrary. It suggests that whereas the "*availability*" of judicial review may be a factor in *favor* of upholding a delegation, the "*preclusion*" of review is not a factor *against* upholding a delegation (*see* Gov't Br. 36–37), but that is like saying, "Heads I win, tails you lose." Either judicial review matters for nondelegation analysis (as courts have repeatedly recognized) or it doesn't. Contrary to the government's claim

(at 37), the Ninth Circuit did not hold in *United States v. Bozarov*, 974 F.2d 1037, 1045 (9th Cir. 1992), that judicial review is irrelevant. While recognizing that "the availability of judicial review is a factor weighing in favor of upholding a statute against a nondelegation challenge," the court held only that "the availability of review is not *always* a constitutional necessity." *Id.* at 1042 (emphasis added); *see id.* ("[P]reclusion of review may *in some cases* be constitutional" (emphasis added)). In *Bozarov* itself, the court emphasized that the statute at issue there "involves matters of foreign policy and national security," which, in light of "the President's traditional dominance in and responsibility for foreign affairs," "counsels in favor of upholding the Act's preclusion of judicial review." *Id.* at 1044 (quotation marks omitted). The government thus has no answer to the mountain of Supreme Court and Sixth Circuit precedent establishing the relevance of judicial review for nondelegation analysis.

Reaching even farther afield, the government argues that treating judicial review as a factor in nondelegation analysis is "inconsistent" with a "line of settled precedent" holding that Congress generally has the power to restrict the jurisdiction of the lower federal courts. Gov't Br. 37–38; *see, e.g.*, *Webster*, 486 U.S. at 597 (holding that a provision "of the National Security Act (NSA) precludes judicial review of the [CIA] Director's termination decisions"). That line of precedent is beside the point, as Plaintiffs have never argued that the preclusion of review *by itself* "creates a nondelegation problem." Gov't Br. 36–37. The problem with the IRA is its unique *combination* of a vast delegation of power to an administrative agency with a dearth of safeguards such as statutory standards, judicial review, and notice-and-comment requirements. The "lack of historical precedent" for that combination is a "telling indication" that it violates separation-of-powers

principles. *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 505–06 (2010) (quotation marks omitted).[13]

At bottom, the purpose of the separation of powers is to "make [g]overnment accountable" and thereby "secure individual liberty." *Boumediene v. Bush*, 553 U.S. 723, 742–43 (2008). The nondelegation doctrine is designed to prevent Congress from "insulating itself from the consequences of hard choices" by transferring important and controversial decisions to agencies. *Tiger Lily, LLC v. U.S. Dep't of Hous. & Urban Dev.*, 5 F.4th 666, 674 (6th Cir. 2021) (Thapar, J., concurring). When Congress not only delegates massive power to an agency but insulates the agency from judicial review or other checks and balances, it further undermines accountability. The concept that multiple layers of accountability-destroying mechanisms can violate the separation of powers, even if one such mechanism by itself might not do so, is at the heart of cases like *Free Enterprise Fund* and *Seila Law*. In *Free Enterprise Fund*, while *one* layer of for-cause removal limitations may not have raised constitutional concerns, the Supreme Court held that a "*dual*" layer of for-cause removal violated the separation of powers. 561 U.S. at 492 (emphasis added). Similarly, in *Seila Law*, the Court held an agency's structure unconstitutional not only because Congress gave the agency very broad policymaking power, but because Congress failed to add robust checks and balances—such as a multi-member body that could mitigate the unilateral discretion of a single director.[14] Just as the "multilevel protection from removal" in *Free Enterprise*

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[13] The government says it "has not argued here" that 42 U.S.C. § 1320f-7 "forecloses judicial review of constitutional claims." Gov't Br. 37 n.9. Even if that carefully worded non-concession could guarantee the availability of some bare minimum of judicial review of agency action for constitutionality, judicial review is also important to ensure that the agency adheres to statutory standards. *See Am. Power & Light*, 329 U.S. at 105. The government does not suggest that the IRA's judicial review bars would permit such review.

[14] The government ignores *Free Enterprise* and *Seila Law* because, the government says, "those cases are about the Appointments Clause" and "Plaintiffs do not bring any appointment or removal claims in this case." Gov't Br. 37 n.10. But the holdings of *Free Enterprise Fund* and *Seila Law* are, like the nondelegation doctrine, based on separation-of-powers principles and the Vesting Clauses. *See Free Enter. Fund*, 561 U.S. at 492 ("We hold that the dual for-cause limitations on the removal of Board members contravene the Constitution's separation of powers."); *Seila Law LLC*

Fund was "contrary to Article II's vesting of executive power in the President," 561 U.S. at 484, the multilevel protection from accountability in this case violates Article I's vesting of "all legislative powers" in Congress.

While discounting the importance of judicial review and other checks and balances, the government also mischaracterizes the IRA as reining in HHS's delegated power. *See* Gov't Br. 34 –36 ("Congress itself 'made virtually every legislative determination' . . . 'which has the effect of constricting the [agency's] discretion to a narrow and defined category.'" (quoting *United States v. Ambert*, 561 F.3d 1202, 1214 (11th Cir. 2009)). Most obviously, while the government applauds Congress for resolving certain "minutiae" and establishing "formulae for calculating ceiling prices," *id.* at 34, it lets Congress off the hook entirely for its unprecedented failure to establish any standard whatsoever for ensuring a price *floor*. Unlike the administrative price-control regimes in the government's own cited nondelegation cases, the IRA does not contain a requirement that prices be "just and reasonable" or "fair and equitable" or any other equivalent guarantee. *Compare Fed. Power Comm'n*, 320 U.S. at 600; *Yakus*, 321 U.S. at 420. Contrary to the government's suggestion, Plaintiffs are not demanding "a specific and binding formula for CMS to use in calculating an offer price." Gov't Br. 36. Rather, Plaintiffs are pointing out the lack of *any* price-setting *standard*—a radical departure from every other federal price-control regime in history.

In that crucial respect and others, Congress did not "define[] the critical terms." Gov't Br. 34. As Plaintiffs have explained (and the government does not contest), the IRA's purported definition of the term "maximum fair price" is completely circular; the "maximum fair price" is defined not by reference to any standard of fairness or reasonableness, but simply as the "price

v. Consumer Fin. Prot. Bureau, 140 S. Ct. 2183, 2191 (2020) ("The question before us is whether this arrangement violates the Constitution's separation of powers"). And Plaintiffs have consistently argued that the IRA's structure violates *both* the nondelegation doctrine and broader separation-of-powers principles. Pl. Br. 3–4, 49, 58–59.

negotiated" (*i.e*., imposed) "pursuant to section 1320f-3." 42 U.S.C. § 1320f(c)(3); *see* Pl. Br. 52. In other words, the "maximum fair price" is whatever HHS says it is—hardly a "narrow and defined" role for the agency. And the IRA's instruction to "aim[] to achieve the lowest maximum fair price for each selected drug" only makes matters worse. Gov't Br. 34 (quoting 42 U.S.C. § 1320f-3(b)(1)). (Despite the government's attempt to amend that statutory instruction on the fly, it does not include the caveat "for which it is able to persuade manufacturers to sign an agreement," Gov't Br. 34.) Without a price floor, the "lowest" price is zero, but Congress couldn't possibly have meant that HHS should aim for "zero," so the instruction is ultimately incoherent.

As Plaintiffs have pointed out (again without rebuttal from the government), Congress also did not define the critical term "drug" in the IRA. Pl. Br. 9. CMS has taken full advantage of this gap, stretching its power by taking a maximal view of what constitutes a single "drug." Revised Guidance at 99–100. As a result, the IRA's price controls will apply to a far greater number of drug products (with separate FDA approvals) than the number of drugs formally "selected."

Without any statutory standard or judicial review to constrain HHS's decisionmaking, the assortment of "factors" and "evidence" for HHS to "consider" in dictating prices simply cannot supply the requisite "intelligible principle." Gov't Br. 35–36. CMS itself has all but conceded that point: the IRA "does not specify how [the agency] should determine an initial offer nor how or to what degree each factor should be considered." CMS, Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments at 47 (Mar. 15, 2023) ("Initial Guidance"); *accord* Revised Guidance at 144. In other words, as with the delegation the Supreme Court struck down in *Schechter*, the agency's discretion is essentially "unfettered." 295 U.S. at 542. The IRA lacks even the "general outline of policy" the Supreme Court found insufficient in

Panama Refining, 293 U.S. at 418. Under fundamental separation-of-powers principles and the nondelegation doctrine, the IRA's unbounded delegation to HHS should likewise be held unconstitutional.

III. The IRA's Price-Control Program Violates the Due Process Clause.

The lack of judicial review, statutory standards, and other traditional procedural safeguards in the IRA leads to a related but independently fatal constitutional defect: the IRA fails to afford manufacturers due process. Whether analyzed under *Michigan Bell* or *Mathews v. Eldridge*, Plaintiffs' procedural due process claim is straightforward. Congress enticed manufacturers to participate in Medicare and Medicaid with promises of market-based pricing and non-interference in third-party negotiations. For decades, manufacturers invested tens of billions of dollars to develop innovative prescription drugs—their hard-earned property—in reliance on those promises. Now, in a stunning about-face, the IRA demands that manufacturers provide access to that property at a government-set price without essential procedural protections against arbitrary, discriminatory, or confiscatory pricing. If manufacturers refuse, they are hit with a crushing penalty—either an astronomical fine or a sweeping cutoff from half of the market that would devastate not only manufacturers but also the tens of millions of Americans who depend on their medicines.

Unable to say anything in defense of the IRA's procedures, the government devotes its response almost entirely to arguing that neither *Michigan Bell*, nor *Eldridge*, nor any due process standard at all applies to the IRA. That is a remarkable claim. According to the government, the IRA exists in a Constitution-free vacuum because it can be framed as a condition on participation in Medicare and Medicaid. The government's theory recognizes no limits on its power to condition access to anything it can characterize as government benefits on the surrender of constitutional rights. Yet as the Supreme Court and the Sixth Circuit have consistently recognized, the government's power to "'grant [a privilege] upon such conditions as it sees fit to impose' . . . 'is

not unlimited; and one of the limitations is that it may not impose conditions which require the relinquishment of constitutional rights.'" *Ostergren v. Frick*, 856 F. App'x 562, 571 (6th Cir. 2021) (quoting *Frost v. R.R. Comm'n*, 271 U.S. 583, 593–94 (1926)); *see* Pl. Br. 27–36. The Supreme Court applied that principle to Tenth Amendment rights in *NFIB*, and the Sixth Circuit applied it to due process rights in *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427, 434–37 (6th Cir. 2005). The government offers no good reason to dispense with that vital limiting principle here. Whether Medicare or Medicaid could be considered "voluntary" before the IRA is beside the point because, like the Medicaid expansion in *NFIB*, the IRA "is in reality a new program" that must be analyzed on its own terms. *NFIB*, 567 U.S. at 554, 582. "Previous [Medicare and] Medicaid amendments simply do not fall into the same category as the one at stake here." *Id*. at 585.

Recognizing that its "voluntariness" argument is also untenable if manufacturers are legally compelled to remain in the IRA's price-control program, the government has sought to use agency "guidance" to override the statutory 11–23-month period that Congress required manufacturers to wait before they can escape from the IRA. But agencies cannot rewrite statutes, let alone through non-binding guidance. The reality, which the government cannot paper over, is that the IRA is "voluntary" neither in the short run nor in the long run.

A. The Government Does Not Even Attempt to Defend the Adequacy of the IRA's Procedures.

A striking feature of the government's brief is that it does not dispute that the IRA's anomalous procedures (and lack thereof) fail to meet the due process requirements set forth in *Michigan Bell* and *Eldridge* if those tests apply here. *See* Pl. Br. 19–27. For example, Plaintiffs argued that the IRA "*invites* arbitrary and confiscatory prices" by failing to provide a price floor, instructing HHS to aim for the "lowest" price, and then insulating the agency's decisions from judicial or administrative review. Pl. Br. 23. In response, the government does not point to any

procedural protection in the IRA, such as a minimum standard of fairness or reasonableness, that "adequately safeguards against confiscatory rates, and therefore, ensures a constitutional rate of return." Pl. Br. 20 (quoting *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 592–93 (6th Cir. 2001)). Plaintiffs also argued that the opportunity to meet with CMS during the "negotiation" process could not substitute for real procedural protections because "[o]ffering to meet is a legally empty gesture without a statutory standard governing the agency's response." Pl. Br. 12. The government does not contend otherwise. Nor does the government deny that "safeguards" that Congress included in every other price-control regime in history until the IRA—such as judicial review—could "substantially mitigate[]" the risk that agency-set prices will be arbitrary or confiscatory. Pl. Br. 26; *see Mathews v. Eldridge*, 424 U.S. 319, 335 (1976). If the tests from *Michigan Bell* or *Eldridge* apply, then, the government has effectively conceded the obvious: the IRA would fail.

B. Regardless of Whether Medicare Is Voluntary, the IRA's Price-Control Program Is Coercive.

The government's argument that the IRA need not satisfy any due process requirements is extreme. As Plaintiffs pointed out, for example, if the government's theory were correct, the IRA "could have instructed CMS to set prices on selected drugs by flipping a coin or spinning a roulette wheel." Pl. Br. 31. Or, for that matter, Congress could have required manufacturers to "take out television ads touting the wisdom and fairness of the IRA." *Id*. Revealingly, the government offers no rebuttal. The government's theory also cannot be reconciled with canonical procedural due process precedents such as *Mathews v. Eldridge* and *Goldberg v. Kelly*. After all, the Social Security disability claimant in *Eldridge* and the welfare recipient in *Goldberg* were not "*legally* compelled to participate" in the government's benefit programs. Gov't Br. 45 (emphasis in original). Yet the Supreme Court held that they were entitled to due process all the same.

The government does not cite a single case holding that the Due Process Clause goes out the window any time a government benefit program is involved. Instead, the government relies principally on statements that participation in Medicare is "voluntary" in decades-old cases assessing distinct claims by differently situated plaintiffs challenging "*other* Medicare conditions" *before the IRA*. Gov't Br. 39–42 (emphasis added).[15] But whether Medicare *itself* could be considered voluntary, apart from the major changes wrought by the IRA, is irrelevant. Even assuming that participation in pre-IRA Medicare was voluntary, and even assuming that due process requirements evaporate whenever a government program is voluntary (contra *Goldberg* and *Eldridge*), these cases prove nothing about Plaintiffs' due process challenge to *the IRA*.

Contrary to the government's suggestion, Plaintiffs do not contend that all modifications to Medicare or Medicaid are impermissibly coercive, or that reimbursement caps of any kind are *per se* coercive. *See* Gov't Br. 40–41. That is a straw man. Rather, as the Supreme Court recognized in *NFIB*, there is a difference between an ordinary Medicare or Medicaid "alter[ation]" and a "dramatic[]" change that "transform[s]" the nature of the program. 567 U.S. at 584. Like the challengers in *NFIB*, Plaintiffs contend that "the [IRA] is in reality a *new* program" that "Congress is forcing [manufacturers] to accept" "by threatening the funds for the *existing* [Medicare and] Medicaid program." *Id.* at 582 (emphasis added). The President touts the IRA as "transformative"[16]

[15] *See, e.g., Baptist Hosp. E. v. Sec'y of HHS*, 802 F.2d 860, 867–69 (6th Cir. 1986) (addressing Takings Clause challenge to HHS reimbursement regulation that disallowed reimbursement for certain costs a hospital incurred in voluntarily providing unpaid care to "non-Medicare patients"); *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 722 (6th Cir. 1991) (concluding that Medicare regulation satisfied due process because it "explicitly provides for judicial review"); *Baker Cnty. Med. Servs., Inc. v. U.S. Att'y Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014) (Takings Clause challenge to Medicare condition requiring provision of care to federal detainees at "the Medicare rate"); *Garelick v. Sullivan*, 987 F.2d 913, 915–16 (2d Cir. 1993) (Takings Clause challenge to particular reimbursement rate for hospital-based anesthesiologists).

[16] Press Release, White House, Fact Sheet: One Year In, President Biden's Inflation Reduction Act is Driving Historic Climate Action and Investing in America to Create Good Paying Jobs and Reduce Costs (Aug. 16, 2023), http://tinyurl.com/yc5chze6.

and HHS lauds it as a "historic law" with "landmark" effect.[17] As with the Medicaid expansion in *NFIB*, "[p]revious Medica[re] amendments simply do not fall into the same category as the one at stake here." *Id*. at 585. The "original" Medicare and Medicaid programs, including Part D, were designed as safety nets to cover prescription drugs for vulnerable populations such as the poor and the elderly, not as sweeping price-control programs intended to leverage the government's regulatory powers and dominant market position to obtain drugs below market value. Indeed, the non-interference clause in Medicare Part D was designed precisely to avert such a "fundamental" shift in mission. Cong. Rec. S15,624 (daily ed. Nov. 23, 2003) (statement of Sen. Grassley). The IRA turns all that on its head, weaponizing manufacturers' reliance on Congress's longstanding promises as an economic "gun to the head." *NFIB*, 567 U.S. at 581. Manufacturers that invested billions of dollars in reliance on the basic terms of the program "could hardly anticipate" that Congress would "transform it so dramatically." *Id*. at 584. Like the Medicaid expansion, the IRA is a "coerci[ve]" "new" program, not a mere extension of a voluntary "existing" program. *Id.* at 582, 585.

Proclaiming that "Spending Clause legislation operates based on consent," Gov't Br. 41, merely "begs the question," *NFIB*, 567 U.S. at 582. The funding recipients in *NFIB* had consented to participate *in Medicaid*. But this did not mean that their challenge to the *expansion* of Medicaid failed; to the contrary, they succeeded, because they had not consented to that transformational expansion. *See id.* The same goes for manufacturers' participation in the IRA's transformation of Medicare for pharmaceuticals. And while the Supreme Court has observed that "*[a]s a general matter*, if a party objects to a condition on the receipt of federal funding, its recourse is to decline

[17] Press Release, HHS, HHS Selects the First Drugs for Medicare Drug Price Negotiation (Aug. 29, 2023), http://tinyurl.com/yscsxmbu.

the funds," *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013) (emphasis added), the government errs by omitting the words "[a]s a general matter" from the quote. Gov't Br. 41. That "general" rule is subject to important exceptions—including where, as here, the condition is "coercive, in the sense of an offer that cannot be refused." *Open Soc'y*, 570 U.S. at 214; *compare NFIB*, 567 U.S. at 585 (holding that the Medicaid expansion crosses the "line where persuasion gives way to coercion" (quotation marks omitted)).

Perhaps recognizing that the IRA would be considered "coercive" under *NFIB*'s reasoning, the government makes various attempts to dismiss that reasoning as irrelevant. *See* Gov't Br. 45–50. None of those attempts is convincing. First, the government tries to cabin *NFIB* as applicable only to the Tenth Amendment rights of states, and not the constitutional rights of other funding recipients. But if a Spending Clause condition is "coercive" for states, it does not magically become "voluntary" when applied to private parties. *See* Pl. Br. 34; *cf. Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (applying concept of "economic dragooning" to private colleges receiving federal funds (quoting *NFIB*, 567 U.S. at 582)). The Supreme Court has applied the same contract-based principles of consent, fair notice, and unfair surprise to Spending Clause conditions imposed on private parties. *Compare NFIB*, 567 U.S. at 576–77 ("Spending Clause legislation [is] much in the nature of a contract" (quotation marks omitted)) *with Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 216 (2022) ("[L]egislation enacted pursuant to the spending power is much in the nature of a contract" (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981))).

Nothing in *NFIB* suggests a contrary approach. The government is conflating the Court's discussion of the Tenth Amendment's anti-commandeering principle, which explained why Congress could not order states to implement the Medicaid expansion *directly*, *see* 567 U.S. at

575–77, with *NFIB*'s voluntariness analysis, which considered whether Congress could nonetheless pressure states to enact the policy *indirectly* by withholding Medicaid funds, *see id.* at 577–85. The latter question—whether the government can force indirectly what it could not "'command directly'" by "deny[ing] a benefit"—is the same question courts ask in other unconstitutional-conditions cases, irrespective of the underlying right at issue. *Perry v. Sindermann*, 408 U.S. 593, 597 (1972) (First Amendment) (quoting *Speiser v. Randall*, 357 U.S. 513, 526 (1958)); *see also, e.g.*, *Open Soc'y*, 570 U.S. at 214 (First Amendment); *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604–05 (2013) (Takings Clause); *Keego Harbor*, 397 F.3d at 436 (Due Process Clause) ("[P]ursuant to the 'unconstitutional conditions' doctrine, [the city] cannot indirectly force [the brewery] to close at 11:00 p.m. by withholding government benefits"). That *NFIB* involved the Tenth Amendment is an observation, not an argument.

Second, the government argues that the *NFIB* coercion inquiry "make[s no] sense" here because, the government says, its enforcement of the IRA is merely a form of market participation. Gov't Br. 46–47. To recite this argument is to refute it. Branding aside, the IRA is plainly an exercise of sovereign regulatory power, not an example of ordinary market participation. No ordinary market participant, even a "well-funded" one (Gov't Br. 47), could impose a 1,900% "excise tax" penalty on a counterparty for refusing to come to an "agreement," as the IRA does. No ordinary market participant could legislate its own takeover of much of the prescription drug market, as Congress did in Medicare Part D. And under the antitrust laws, having obtained such a dominant market position, no ordinary market participant could evade scrutiny for wielding its dominance over nearly 50% of the market to obtain access to a counterparty's goods at a preferred price. *Cf. Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 13–14 (1984) ("[W]e have condemned tying arrangements when the seller has some special ability—usually called 'market

power'—to force a purchaser to do something that he would not do in a competitive market."), *abrogated on other grounds by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006). HHS has also exploited its regulatory powers to require the provision of confidential and proprietary information that a manufacturer would not ordinarily share with another market participant, *see* 42 U.S.C. § 1320f-2(a)(4), backed by civil monetary penalties of $1 million per day, *id.* §§ 1320f-6(c), 1320f-2(a)(5). A mere market participant that, unlike the government, doesn't make or enforce the law could not dream of such tools of coercion.

Moreover, the government's cases on the "market participant" doctrine have no bearing on whether *NFIB* applies here. Gov't Br. 47. Most of the cases address whether States can raise a market-participant defense to claims of preemption or dormant Commerce Clause violations. *See, e.g.*, *Chamber of Com. v. Brown*, 554 U.S. 60, 70 (2008) (preemption); *Bldg & Constr. Trades Council of Metro. Dist. v. Associated Builders & Contractors of Mass./R.I., Inc.*, 507 U.S. 218, 229 (1993) (preemption); *Brooks v. Vassar*, 462 F.3d 341, 358 (4th Cir. 2006) (dormant Commerce Clause). Those questions are not relevant here. As for *Biden v. Missouri*, contrary to the government's suggestion, that case mentioned neither *NFIB* nor the market-participant defense. 595 U.S. 87 (2022) (per curiam). The Court merely held that "the Secretary did not exceed his statutory authority" to impose "health and safety" conditions on Medicare and Medicaid funding recipients. *Id.* at 93–96. If anything, *Biden v. Missouri* underscores how different the IRA is from the kinds of conditions the government has "routinely" imposed in the past. *Id.* at 94.[18]

[18] The government also makes passing references to the "340B program" and EMTALA, Gov't Br. 49, but the IRA bears no resemblance to either. The 340B program was designed to further the purposes of Medicaid by facilitating access to discounted drugs for indigent and uninsured patients. *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023). Moreover, unlike the IRA, the 340B program has an administrative dispute resolution mechanism, along with judicial review. *See* 42 U.S.C. § 256b(d)(3). And EMTALA's limited mandate to provide emergency room care to stabilize patients in dire need, *see Moses v. Providence Hosp. & Med. Ctrs., Inc.*, 561 F.3d 573, 579 (6th Cir. 2009), hardly changed the fundamental nature of the programs.

Finally, the government contends that the IRA's price-control program does not "'take the form of threats to terminate other significant independent grants'" and instead only "'govern[s] the use of' Medicare funds for the selected drugs." Gov't Br. 48–49 (quoting *NFIB*, 567 U.S. at 580). If only that were true. Congress *could* have designed the IRA not to threaten Medicare and Medicaid coverage of a manufacturer's *other* drugs. Instead, to ensure that manufacturers would be forced to "agree" to whatever low price HHS set on a selected drug, Congress tied continued coverage of manufacturers' other drugs to manufacturers' "agreement" to price controls on the selected drug. The only way for a manufacturer of a selected drug to escape the price-control regime and avoid the IRA's crushing "excise tax" is to surrender "other significant independent grants"—*i.e.*, Medicare and Medicaid coverage of the manufacturer's entire portfolio of drugs. Like the catch-22 imposed on the states in *NFIB*, that is "no real option." 567 U.S. at 582.

Having failed to parry *NFIB*, the government's other efforts to portray the IRA as voluntary fare no better. For example, while apparently acknowledging that the unconstitutional conditions doctrine prohibits the government from conditioning benefits on the surrender of due process, the government says that Plaintiffs' members have no due process rights in the first place for lack of a "liberty or property interest." Gov't Br. 50–51 (quoting *Keego Harbor*, 397 F.3d at 434); *see also id.* at 52–54. Yet the liberty and property interests at stake here are readily apparent. Whereas in *Keego Harbor* the court had to work out whether state law gave the brewery a property interest in certain hours of operations, *see* 397 F.3d at 435, here the underlying property is quite concrete: manufacturers' prescription drugs. As owners of the drugs, manufacturers' "'bundle' of [] rights" includes "'the rights to possess, use and dispose of'" those drugs. *Horne v. Dep't of Agric.*, 576 U.S. 350, 361–62 (2015) (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 435 (1982)). It is a "well-settled general principle that the right of the owner of property to fix the

price at which he will sell it is an inherent attribute of the property itself, and as such is within the protection of the Fifth . . . Amendment[]." *Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936); *see also King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995) ("Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace."). "By penalizing high prices—and thus limiting the full exercise of the exclusionary power that derives from a patent—the [IRA] . . . re-balance[s] the statutory framework of rewards and incentives . . . as it relates to inventive new drugs." *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1374 (Fed. Cir. 2007). Price-control regimes have always been subject to procedural due process scrutiny, even in wartime emergencies and even when the price-regulated parties are not legally compelled to sell their products. *See, e.g.*, *Yakus*, 321 U.S. at 431–33; *Bowles v. Willingham*, 321 U.S. 503, 520 (1944) (noting that "property rights are involved").

Furthermore, "'property' interests subject to procedural due process protection are not limited by a few rigid, technical forms." *Perry*, 408 U.S. at 601. Such interests can be created through statutes, "explicit" or "implied" contracts, "'policies and practices,'" or "rules and understandings" that are "promulgated and fostered by [government] officials." *Id.* at 601–03 (quoting *Sindermann v. Perry*, 430 F.2d 939, 943 (5th Cir. 1970)). When manufacturers invested billions of dollars to develop drugs in reliance on Congress's promises of market-based pricing and non-interference in private negotiations, *see* Pl. Br. 6–7, they did so with far more than a "mere subjective 'expectancy'" in the continuation of that basic bargain, *Perry*, 408 U.S. at 602–03 (quoting *Sindermann*, 430 F.2d at 943). Indeed, when Congress created Medicare Part D, it prohibited HHS from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] sponsors." 42 U.S.C. § 1395w-111(i). Part D's sponsors

called that "noninterference" commitment a "fundamental protection" against "price fixing by the CMS bureaucracy." 149 Cong. Rec. S15,624 (Nov. 23, 2003) (statement of Sen. Grassley); *see also, e.g.*, 149 Cong. Rec. S15,707 (Nov. 24, 2003) (statement of Sen. Santorum) (noting that without the clause, the agency's newfound "market power" would enable it to "dictate a price" for "most pharmaceutical products"). Manufacturers therefore have a "legitimate claim of entitlement" based on years of "rules and understandings, promulgated and fostered by" the government. *Perry*, 408 U.S. at 602–03.

The government also repeats its empty assertions that manufacturers can simply "divest" their interests in their drugs or "stop selling" vital medicines to Medicare beneficiaries. S*ee* Gov't Br. 7–8, 42, 44, 48–49. Plaintiffs have already explained why those purported fixes are unworkable, *see* Pl. Br. 35–36, and the government offers no rebuttal. For instance, the government does not deny the impracticability of quickly offloading such complex assets or the impossibility of getting fair market value for a drug that is *already* subject to price controls. *See id.* Nor would divesting "to a subsidiary" be of any help; that would simply transfer the harm from one member of a corporate family to another. Gov't Br. 42.

And "leaving Medicare and Medicaid entirely" is hardly "a more straightforward option" for companies like Pharmacyclics. *Id.* at 49. In addition to the immediate costs to Pharmacyclics itself, which would also harm its parent company AbbVie, that so-called "option" would devastate the entire AbbVie corporate family (and the many millions of patients it serves). That is because under the government's self-described "longstanding policy," which HHS and CMS are promulgating a regulation to codify, affiliated entities are treated together for purposes of Medicare and Medicaid such that an entire corporate family must be either "all in" or "all out." Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates

Under the Medicaid Drug Rebate Program, 88 Fed. Reg. 34,238, 34,255–56 (May 26, 2023). As a subsidiary of AbbVie, Pharmacyclics cannot withdraw without also triggering the loss of coverage for every other prescription drug in the AbbVie family's collective portfolios. Pharmacyclics' withdrawal would mean the loss of coverage for more than 85 other critical medicines—a cataclysmic result for AbbVie as well as the many Americans who depend on those medicines. *See* Pl. Br. 15 & n.9, 33–34. Plaintiffs explained all of this, so the government's resort to half-formed suggestions about divesting selected drugs to a subsidiary—without acknowledging its "longstanding policy" of disregarding the corporate form within a corporate family—is baffling.[19]

C. CMS Cannot Nullify the Statutory 11-to-23-Month Waiting Period for Withdrawal from Medicare and Medicaid.

Even apart from the IRA's coerciveness under *NFIB* and the unconstitutional conditions doctrine, manufacturers are legally compelled to remain in the price-control program during the statutory window of 11 to 23 months before a withdrawal from federal healthcare programs takes effect. *See* Pl. Br. 28–30. CMS's non-binding guidance, issued in response to litigation, purports to override that statutory requirement by conflating Congress's procedures for "termination by the Secretary" with the separate and very different procedures for "termination by the manufacturer." *Id.*; *see* Gov't Br. 43–44. Plaintiffs have already shown that the agency's rush "repair" job falls apart upon examination, *see* Pl. Br. 28–30, and the government makes only a fleeting attempt to rebut Plaintiffs' careful interpretation of the statutory text and structure, *see* Gov't Br. 42–45.

Zeroing in on a snippet of the relevant language and quoting a case about a completely different statute, the government argues that the phrase "good cause" in the provision for

[19] Citing a lone news article (hidden behind a paywall), the government suggests that some manufacturers have "[r]ecogniz[ed] the viability of" withdrawing from Medicare and Medicaid. Gov't Br. 42 n.12. That is not what the article says. In fact, the article simply notes that, as an unfortunate result of the IRA, some companies may be less likely to focus on developing drugs that serve the Medicare population.

terminations by the Secretary is "flexible and capacious." *Id.* at 44 (quoting *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 429 n.2 (2023) (False Claims Act)). But unlike the "good cause" provision in *Polansky*, the sentence in which "good cause" appears here refers to "*a knowing and willful violation . . . or other* good cause." 42 U.S.C. § 1395w-114a(b)(4)(B(i) (emphasis added); *accord id.* § 1395w-114c(b)(4)(B)(i). As the Sixth Circuit has held, "the meaning and boundaries of the term 'good cause'"—like any other statutory term—must "be gathered from context." *Owen of Ga., Inc. v. Shelby Cnty.*, 648 F.2d 1084, 1092 (6th Cir. 1981) ("[T]he phrase 'good cause' must be read *ejusdem generis* to refer to other factors of the same genre as those enumerated by the specific words"). The context here strongly favors reading "other good cause" to refer to "other factors of the same genre" (*i.e.*, misconduct that might warrant termination), and the broader statutory structure provides even further confirmation. For example, among other anomalies, whereas Congress gave manufacturers a "hearing" only when the Secretary seeks termination for misconduct or similar good cause, CMS's backwards interpretation would give a manufacturer a hearing on its *own* request for a termination. That absurd redundancy highlights how CMS has twisted Congress's design. *See* Pl. Br. 30 & n.16.[20]

D. *Verizon* Only Reinforces Plaintiffs' Procedural Due Process Arguments Under *Michigan Bell* and *Eldridge*.

In yet another effort to avoid scrutiny of the IRA's inadequate procedures, the government renews its attempt to convert Plaintiffs' *due process* challenge into a *Takings Clause* claim that is somehow foreclosed by a takings discussion in a *statutory interpretation* case, *Verizon Commc'ns,*

[20] As a fallback to CMS's attempted statutory rewrite, the government suggests that manufacturers can afford to wait 11 to 23 months anyway because the IRA's prices do not take effect until January 1, 2026. *See* Gov't Br. 44–45. That is a red herring. The IRA's "excise tax" was designed to kick in much sooner—on October 2, 2023, just a few weeks after the first round of drug selection—if manufacturers did not "agree" in advance to "provide access" to selected drugs at whatever the government later deems the "maximum fair price." *See* 26 U.S.C. § 5000D(b); 42 U.S.C. §§ 1320f-2(a), 1320f(d). Surely the government is not suggesting that manufacturers should engage in "gamesmanship," Gov't Br. 19, by signing an "agreement" with CMS and then turning around the next day and violating the "agreement" by initiating a withdrawal from Medicare and Medicaid.

Inc. v. FCC, 535 U.S. 467 (2002). Plaintiffs thoroughly rebutted that argument at the preliminary injunction stage, *see* Dkt. 49 at 2, 6–8, and it has not improved here.

In *Verizon*, the Court addressed only a takings issue. The Court said that it had "never considered a *taking[s] challenge* on a ratesetting methodology without being presented with specific rate orders alleged to be confiscatory." 535 U.S. at 524 (emphasis added). But Plaintiffs do not bring a takings challenge; they bring a due process claim under *Michigan Bell* and *Eldridge*—a canonical procedural due process case. *See* FAC ¶¶ 182–212. Furthermore, the district court in *Michigan Bell* expressly distinguished the plaintiffs' takings claim from their claim that "the statute on its face violates the Due Process Clause because it provides *no mechanism by which the Plaintiffs may seek relief from any allegedly confiscatory rates*," and on appeal the Sixth Circuit considered only the due process claim. *Michigan Bell Tel. Co. v. Engler*, No. 00-cv-73207, 2000 U.S. Dist. LEXIS 20876, at *47 n.12 (E.D. Mich. Sept. 14, 2000) (emphasis altered)).

Indeed, if anything, *Verizon* is yet another case that underscores the lack of "constitutionally sufficient procedures" in the IRA. FAC ¶ 183. *Verizon* involved a statute that, unlike the IRA, included the classic "just and reasonable" standard for price controls, 47 U.S.C. § 252(d)(1), as well as a mechanism by which companies could "show that the pricing methodology, as applied to them, will result in confiscatory rates." *Verizon*, 535 U.S. at 528 n.39 (quotation marks omitted). And unlike the IRA, the statute provided judicial review. *See id.* at 524.

Moreover, because the due-process deficiencies in the IRA are clear on the face of the statute, Plaintiffs do not need to wait to see "whether any of their members will agree to prices that are so low as to threaten their 'financial integrity.'" Gov't Br. 56 (quoting *Verizon*, 535 U.S. at 524). Having abandoned its ripeness objection, the government tries to recast it as an argument that Plaintiffs "cannot satisfy the standard for a facial challenge." *Id.* But there is "no set of

circumstances," *id.*, under which the IRA's lack of procedural safeguards can pass the *Eldridge* test or satisfy *Michigan Bell*. *See supra* section III.A; Pl. Br. 19–27; *Michigan Bell*, 257 F.3d at 595 n.4 ("[I]t is axiomatic that due process guarantees a fair and reasonable regulatory rate, not just the possibility of acquiring such a rate from an authority selecting rates within a prescribed range containing confiscatory and fair rates."). Indeed, the government does not even attempt to justify the IRA's procedures under the tests mandated by those binding precedents.[21]

IV. The IRA's Compelled-Speech Requirements Violate the First Amendment.

The IRA is more than a price-control regime; it is also a speech-control regime. To enhance the IRA's illusion of voluntariness and cover up its fundamental constitutional defects, Congress enlisted manufacturers in a public relations campaign. Whereas "a typical price regulation . . . would simply regulate the amount that a [business] could collect," the IRA "is different." *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017). The IRA forces manufacturers to declare publicly that they "agree" to the government-set price and that it is the "maximum fair price." 42 U.S.C. § 1320f(d)(1); *see* CMS, Medicare Drug Price Negotiation Program Agreement ("CMS Template") at 2, *available at* http://tinyurl.com/2ukcv839. That "involuntary affirmation of objected-to beliefs," which advances no legitimate government interest, is unconstitutional compelled speech. Pl. Br. 45–48 (quoting *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.*, 138 S. Ct. 2448, 2464 (2018)).

[21] This case is a far cry from *United States v. Salerno*, where the challengers sought to invalidate Bail Reform Act procedures that would be applied in a wide variety of different contexts to differently situated criminal defendants. The Court rejected a due process challenge to that statute only after carefully considering its "extensive safeguards" and "procedural protections"—including trial-like procedural rights, a neutral decisionmaker, and provisions for judicial review—and finding that they would be "adequate to authorize the pretrial detention of at least some [persons] charged with crimes." 481 U.S. 739, 749–52 (1987) (quotation marks omitted). Here, the IRA's dearth of procedural safeguards makes the regime inadequate for imposing price controls on *any* manufacturer. *See supra* Section III.A; Pl. Br. 19–27.

The government argues that the IRA's compelled speech is shielded from First Amendment scrutiny as "'plainly incidental to the . . . regulation of conduct.'" Gov't Br. 56–57 (quoting *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.* (*FAIR*), 547 U.S. 47, 62 (2006)). But just the opposite is true. The compelled speech here is entirely gratuitous, not incidental—let alone *plainly* incidental—because Congress could easily have established a price-control regime without the use of a so-called "agreement" regarding so-called "negotiations" and a so-called "maximum fair price." Contrary to the government's suggestion, the IRA therefore clearly "implicate[s] the First Amendment . . . more than 'typical price regulation,' which 'would simply regulate the amount [of money] that a [manufacturer] could collect.'" Gov't Br. 57 (quoting *Expressions Hair Design*, 581 U.S. at 47). Like the statute the Supreme Court struck down in *Expressions Hair Design*, the IRA's compelled-speech mandate "regulate[s] . . . how sellers may communicate their prices." 581 U.S. at 47–48 (rejecting argument that law regulating communication of prices "is nothing more than a mine-run price regulation"). The IRA requires manufacturers to use the loaded term "maximum fair price," which is obviously "designed to send a particular message about the charge": that it is not only fair, but the *maximum* fair price (such that any higher price is *unfair*). *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 292 (D.C. Cir. 2019). In "regulating the communication of prices" rather than only "prices themselves," the IRA "regulates speech." *Expressions Hair Design*, 581 U.S. at 48.[22]

The government does not appear to dispute that, if the IRA compels speech, the compelled-speech requirements would fail any level of First Amendment scrutiny, let alone strict scrutiny.

[22] Although the government says that Medicare "routinely uses agreements that health care providers or other entities sign," Gov't Br. 57, none of the agreements it identifies compels the use of anything like the loaded terminology of the IRA "agreement," which requires manufacturers "to endorse—implicitly or explicitly" a controversial government policy as fair. *Thompson v. Marietta Educ. Ass'n*, 972 F.3d 809, 812–13 (6th Cir. 2020) (quotation marks omitted).

See Pl. Br. 46. That is no surprise. The government does not identify a single other price-control regime that, like the IRA, is structured to put the government's propaganda about the "fairness" of its policy in the regulated party's mouth. The only conceivable purpose of the IRA's ventriloquism is to deceive the public about the true nature of the price-control regime. Nor is it any defense that the "agreement uses statutory terms" and contains a disclaimer (buried on the fourth page) stating that those terms are not necessarily used in their "colloquial" sense. Gov't Br. 58 (quotation marks omitted). "[T]he statutory definition" of a loaded term "cannot save" a compelled-speech requirement. *Nat'l Ass'n of Mfrs. v. SEC*, 800 F.3d 518, 529–30 (D.C. Cir. 2015). "[If the law were otherwise, there would be no end to the government's ability to skew public debate by forcing companies to use the government's preferred language." *Id.* at 530 (quotation marks omitted). "For instance, companies could be compelled to state that their products are not environmentally sustainable or fair trade if the government provided 'factual' definitions of those slogans—even if the companies vehemently disagreed that their [products] were 'unsustainable' or 'unfair.'" *Id.* (citation omitted). Here, likewise, manufacturers "vehemently disagree[]" that they are voluntarily acceding to a price they consider "fair," but they are compelled to use the government's "preferred language" in order to "skew public debate" about the IRA. Because manufacturers are forced "'to endorse'—either implicitly or explicitly—'ideas they find objectionable,'" the IRA's compelled speech requirements violate the First Amendment. *Thompson*, 972 F.3d at 813 (quoting *Janus*, 138 S. Ct. at 2464).

Alternatively, the government argues that the IRA's demand that manufacturers endorse CMS prices as fair is not "compelled" because, the government says, the IRA price-control program is "voluntary." Gov't Br. 59–60. That argument fails for multiple reasons. First, as discussed above and in Plaintiffs' opening brief, the program is coercive, not voluntary. *See supra*

Section III; Pl. Br. 27–35. The government euphemistically refers to the IRA's demands as an "invitation" to manufacturers, Gov't Br. 60; but only in doublespeak can an "invitation" be backed by a 1,900% "tax" penalty (among other sanctions) for politely declining. Second, a speech condition may be unconstitutional *either* because it is coercive *or* because it is extraneous to the core purposes of the government's spending program. Under the unconstitutional conditions doctrine, the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests—especially, his interest in freedom of speech." *Lucas v. Monroe Cnty*., 203 F.3d 964, 972 (6th Cir. 2000) (quoting *Perry*, 408 U.S. at 597); *accord FAIR*, 547 U.S. at 59. As the Supreme Court has explained, even if a speech condition is *not* "actually coercive, in the sense of an offer that cannot be refused," the condition may be unconstitutional if, rather than "specify[ing] the activities Congress wants to subsidize," it "seek[s] to leverage funding . . . outside the contours" of that core program. *Open Soc'y*, 570 U.S. at 214–15.

Here, the IRA's speech conditions are not only coercive, but impermissibly extraneous. Requiring manufacturers to mime the government's message about what prices are fair does not "specify the activities Congress wants to subsidize," *id.*, because unlike, say, subsidy programs that promote speech about the dangers of smoking or the importance of taking care of military veterans, the core function of the IRA is to control prices, not subsidize speech. *Compare, e.g.*, *Regan v. Tax'n With Representation of Washington*, 461 U.S. 540 (1983) (upholding subsidy condition that funded lobbying only by veterans organizations, not other charities). The IRA's speech requirements are completely unnecessary to the operation of price controls. Those requirements thus impermissibly seek to regulate speech "outside the contours" of the price-control program. *Open Soc'y*, 570 U.S. at 214–15.

The government counters that the CMS "agreements" are the "core mechanisms" by which the agency's price-setting will proceed. Gov't Br. 60. But price-setting does not require sham "agreements," much less a coerced endorsement of the mandated price as "fair"; Congress made a deliberate choice to hide its coercive price controls behind a façade of consent. *See Open Soc'y*, 570 U.S. at 214–15 ("Congress cannot recast a condition on funding as a mere definition of its program in every case, lest the First Amendment be reduced to a simple semantic exercise" (quotation marks omitted)). Imposing price controls through phony "agreements," and requiring manufacturers to call the resulting prices the "maximum fair price," is nothing more than a public-relations ploy designed to "skew public debate." *Nat'l Ass'n of Mfrs.*, 800 F.3d at 530. Manufacturers have a "First Amendment right to avoid becoming the courier for such message," *Wooley v. Maynard*, 430 U.S. 705, 717 (1977), and the government cannot "deny a benefit" to them on that basis, *Perry*, 408 U.S. at 597. The IRA's compelled speech requirements are unconstitutional.

V. The IRA's "Excise Tax" Violates the Excessive Fines Clause and Exceeds Congress's Enumerated Powers.

To ensure that manufacturers comply with its unconstitutional price-control regime, Congress equipped the IRA with a giant hammer: the draconian so-called "excise tax" that quickly rises to 1,900% on sales of a manufacturer's drug. *See* 26 U.S.C. § 5000D(b)(1)–(4). That impossibly steep penalty is unconstitutional for two basic reasons. First, the penalty is so disproportionate that it violates the Excessive Fines Clause. Second, because the penalty is not a true tax, it falls beyond Congress's legislative powers under Article I of the Constitution. Neither of the two potential sources of Article I authority put forward by the government—the taxing power and the power to regulate interstate commerce—can support the enactment of a 1,900% penalty for failing to engage in an unwanted transaction.

A. The "Excise Tax" Violates the Excessive Fines Clause.

1. The government first tries to avoid application of the Excessive Fines Clause by denying that the IRA's so-called "excise tax" is a "fine." Gov't Br. 61–68. But whether a so-called "excise tax" is a "fine" cannot depend on how Congress labeled it. Otherwise, Congress could always evade the Excessive Fines Clause by describing fines as "taxes." The test for whether a monetary exaction is a "fine" therefore depends on its substance: "Whether a governmental exaction is subject to the limitations of the Excessive Fines Clause depends upon whether the exaction "'constitutes payment to a sovereign as punishment for some offense.'" *Moser v. United States*, 166 F.3d 1214, 1998 WL 833714, at *1 (6th Cir. 1998) (quoting *Austin v. United States*, 509 U.S. 602, 622 (1993)). Notably, a monetary demand is a "fine" even if it is only "*in part*" punitive. *F.P. Dev., LLC v. Charter Twp. of Canton*, 16 F.4th 198, 209 (6th Cir. 2021) ("[A] monetary demand that is retributive *or deterrent and thus intended to punish, even in part*, is subject to the limitations of the Excessive Fines Clause" (emphasis added) (citing *Austin*, 509 U.S. at 621)). In contrast, a monetary demand is only "wholly remedial" (*i.e.*, not even partially punitive) when it is "related *only* to 'damages sustained by society or to the cost of enforcing the law.'" *Id*. (emphasis added) (quoting *United States v. Ward*, 448 U.S. 242, 254 (1980)).

Here, the IRA's "excise tax" is indisputably "deterrent and thus intended to punish" (*at least* "in part") noncompliance with the IRA's demands. *Id.* That much is obvious from the face of the statute, both because of the prohibitively high rate and because, unlike an ordinary excise tax on cigarettes or alcohol, it "seeks to bring [parties] into compliance with a regulations." *Stevens v. City of Columbus*, No. 2:20-cv-01230, 2021 WL 3562918, at *4 (S.D. Ohio Aug. 12, 2021); *see Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) ("It is very clear that the 'excise tax' is not imposed for revenue but exacted as a penalty to compel compliance with the regulatory provisions of the act"). Indeed, the "excise tax" provision is titled "Designated drugs *during noncompliance*

periods," and it is expressly triggered by "noncompliance periods" tied to manufacturers' compliance with various IRA mandates, such as the requirements to turn over information demanded by HHS, to "negotiate" with HHS, and to "agree" to the agency's "maximum fair price." 26 U.S.C. § 5000D (emphasis added). The punitive nature of the "tax" is also evident from the fact that Congress's own budget office and the Joint Committee on Taxation projected that it would raise *zero* revenue—because the tax will so effectively deter manufacturers from failing to comply with the IRA. *See supra* at 23.

Ignoring the Supreme Court's flexible, functional approach to the scope of the Excessive Fines Clause, the government argues that the "excise tax" is altogether immune from scrutiny because it is labeled a "tax" and "has no connection to a criminal offense or criminal proceedings." Gov't Br. 61–62. That is not the controlling test. While the government has long sought to limit the Excessive Fines Clause to criminal proceedings, the Supreme Court has squarely rejected that narrow understanding of the constitutional right. "[T]he question is not, as the United States would have it, whether [an exaction] is *civil or criminal*, but rather whether it is *punishment*." *Austin*, 509 U.S. at 606–10 (emphasis added) (reviewing the text, history, and purposes of the Excessive Fines Clause); *accord United States v. Ursery*, 518 U.S. 267, 281 (1996) ("We . . . reject[ed] the argument that the Excessive Fines Clause was limited solely to criminal proceedings"). So long as the exaction "serves *in part* to punish" (*e.g.*, to deter non-compliance), it implicates the Excessive Fines Clause. *Austin*, 509 U.S. at 617; *see Timbs v. Indiana,* 139 S. Ct. 682, 689 (2019) (similar); *United States v. Bajakajian*, 524 U.S. 321, 329 (1998) (noting that deterrence "has traditionally been viewed as a goal of punishment"); *Tyler v. Hennepin County*, 598 U.S. 631, 649–50 (2023) (Gorsuch, J., joined by Jackson, J., concurring) ("Economic penalties imposed to deter willful noncompliance with the law are fines by any other name").

Furthermore, contrary to the government's suggestion, Gov't Br. 62–64, the Constitution's fundamental protection against exorbitant penalties does not turn on mere semantics; the Excessive Fines Clause applies to all "*monetary demands*" intended at least in part to punish (whether or not they are *also* intended to raise revenue). *F.P. Dev.*, 16 F.4th at 209 (emphasis added). Although the Sixth Circuit has observed in the Double Jeopardy Clause context that "taxes *historically* have not been viewed as punishment," Gov't Br. 64 (emphasis added) (quoting *United States v. Beaty*, 147 F.3d 522, 525 (6th Cir. 1998)), as the court went on to explain (in a portion of the opinion the government omits), that is only because "taxes are *typically* different because they are *usually motivated by revenue-raising, rather than punitive, purposes*." *Beaty*, 147 F.3d at 525 (emphasis added). The IRA's "excise tax" bears no resemblance to the modest gambling taxes in *Beaty*. And unlike in *Beaty*, which considered whether those taxes constituted "*criminal* . . . punishment" for purposes of the Double Jeopardy Clause, the question here is whether the "excise tax" is "at least *in part*" punitive such that it implicates the Excessive Fines Clause. *Austin*, 509 U.S. at 610 (emphasis added); *see F.P. Dev.*, 16 F.4th at 209.

The government also spills a great deal of ink on two other Double Jeopardy Clause cases: *Dep't of Revenue v. Kurth Ranch*, 511 U.S. 767 (1994), and *Dye v. Frank*, 355 F.3d 1102 (7th Cir. 2004). Gov't Br. 65–67. As the government acknowledges (at 65), both cases held that a so-called "tax" constituted "punishment" for purposes of the Double Jeopardy Clause. The government argues that the cases are nonetheless distinguishable because the taxes in those cases were "related to criminal offenses." *Id*. But again, the government is conflating the Excessive Fines Clause, which is *not* "limited solely to criminal proceedings," *Ursery*, 518 U.S. at 281, with the Double Jeopardy Clause, which "protects only against the imposition of multiple *criminal* punishments for the same offense," *Hudson v. United States*, 522 U.S. 93, 99 (1997). Although the clauses

involve overlapping questions about what constitutes "punishment" (which is why Plaintiffs cited case law on both clauses in their opening brief), the reach of the Excessive Fines Clause is broader in that its limitation on excessiveness applies to all government exactions, civil or criminal, that are even "partially" punitive. *Timbs*, 139 S. Ct. at 689; *Austin*, 509 U.S. at 610.[23]

Indeed, in a body of case law the government ignores, numerous courts have held that civil penalties are subject to scrutiny under the Excessive Fines Clause. *See, e.g.*, *United States v. Gurley*, 384 F.3d 316, 318–19, 325 (6th Cir. 2004) (applying Excessive Fines Clause scrutiny to civil penalty for failure to respond to EPA information requests); *WCI, Inc. v. Ohio Dep't of Pub. Safety*, 774 F. App'x 959, 966–67 (6th Cir. 2019) (civil penalty imposed by Ohio Liquor Control Commission); *United States v. Aleff*, 772 F.3d 508, 511–12 (8th Cir. 2014) (holding that False Claims Act penalties, although not "punishment" under the Double Jeopardy Clause, are sufficiently punitive to implicate the Excessive Fines Clause); *Grashoff v. Adams*, 65 F.4th 910, 916–18 (7th Cir. 2023) (applying Excessive Fines Clause scrutiny to civil penalty for violation of income-reporting requirement); *Pimentel v. City of Los Angeles*, 974 F.3d 917, 921–22 (9th Cir. 2020) (treating municipal parking penalties as "fines"); *Yates v. Pinellas Hematology & Oncology, P.A.*, 21 F.4th 1288, 1306–14 (11th Cir. 2021) (False Claims Act civil penalties); *United States v. Mackby*, 261 F.3d 821, 830–31 (9th Cir. 2001) (same); *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 387–89 (4th Cir. 2015) (same).

[23] Before the Supreme Court decided *Ursery*, 518 U.S. at 286, some lower courts had read *Austin* to mean that "the method of determining whether the forfeiture constitutes punishment is identical . . . for purposes of the Double Jeopardy Clause and the Eighth Amendment [Excessive Fines Clause]." *United States v. $405,089.23 U.S. Currency*, 33 F.3d 1210, 1219 n.8 (9th Cir. 1994); *see also United States v. Alt*, 83 F.3d 779, 783–84 (6th Cir. 1996) (per curiam) (stating in dicta, in case involving ordinary tax penalty with "remedial" purpose, that "the test for 'punishment' is the same under both doctrines"). But in *Ursery*, the Supreme Court rejected any conflation of the two clauses, explaining that "*Austin* was decided solely under the Excessive Fines Clause of the Eighth Amendment, a constitutional provision which we never have understood as parallel to, or even related to, the Double Jeopardy Clause of the Fifth Amendment." *Ursery*, 518 U.S. at 286; *see United States v. $273,969.04 U.S. Currency*, 164 F.3d 462, 466 (9th Cir. 1999) (per curiam) ("[A] civil sanction that does not implicate the Double Jeopardy Clause may still be punitive for purposes of the Excessive Fines Clause.").

In addition to muddling the law, the government misstates salient factual points. For example, the government incorrectly asserts that whereas the tax in *Kurth Ranch* was "a *multiple*" of the sales revenue, the IRA's "excise tax" is only a "a *fraction*" of revenue. Gov't Br. 67 & n.21. As explained above, the government's math is mistaken. *See supra* Section I.C.2. At its highest level of 19 times revenue, the IRA's "excise tax" is a much greater multiple than the punitive taxes in *Kurth Ranch* (approximately four times revenue) and *Dye* (five times revenue).

2. The government's attempt to deny that the "excise tax" is "excessive" similarly falls flat. *See* Gov't Br. 69–70. The test for excessiveness is simple and well-established: the amount of the exaction is unconstitutionally excessive if it is "grossly disproportionate" to the gravity of the offense. *Bajakajian*, 524 U.S. at 334. Here, the "excise tax" starts at over 185% of the selected drug's pre-tax price and quickly rises to 1,900% of the pre-tax price. *See supra* section I.C.2. The government does not appear to dispute that a penalty of 1,900%, or even 185%, would be grossly disproportionate relative to the "offense" of declining to submit to the IRA's arbitrary price-control regime. Indeed, the government briefly suggests that the enormous chasm between the amount of the exaction and the reprehensibility of the conduct it targets is a reason *not* to apply the Excessive Fines Clause at all, *see* Gov't Br. 68–69—before backtracking and complaining that manufacturers' desire to maintain the market-based status quo is reprehensible after all because "the fisc will likely incur significant losses" if they do not agree to be extorted, Gov't Br. 69–70.

Rather than try to defend the IRA's stratospheric penalty on its own terms, the government tries to bring it down to earth by again pretending that it is "only" 65% to 95%. Gov't Br. 70. Plaintiffs have debunked that fallacy. *See supra* Section I.C.2. If Congress had wanted to impose a 65% or 95% sales tax, it could have done so, without needing a convoluted statutory formula. But that is not what Congress did. As explained, the IRA's "applicable percentages" of 65% and

95% translate to penalties on a manufacturer's revenue of 185.71% and 1,900%. *Id.* Those fines are manifestly draconian and grossly disproportionate to the "noncompliance" they are designed to punish.[24]

B. The "Excise Tax" Exceeds Congress's Enumerated Powers.

Because the so-called "excise tax" is actually an excessive penalty rather than a genuine "tax," it does not qualify as an exercise of Congress's taxing power. Nor can it be justified under the Commerce Clause, which gives Congress only the power to *regulate* commerce—not to *compel* it. The government's arguments to the contrary are unconvincing, and the government does not identify any other potential source of legislative authority. The so-called "excise tax" therefore exceeds the "defined" and "limited" powers granted to Congress in Article I of the Constitution. *United States v. Rife*, 33 F.4th 838, 844 (6th Cir. 2022) (quoting *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 176 (1803)).

1. The Taxing Clause gives Congress the power to "lay and collect Taxes, Duties, Imposts, and Excises" in order to "pay the Debts and provide for the common Defence and general Welfare of the United States." U.S. Const. art. I, § 8, cl. 1. As the IRA itself makes clear, Congress enacted the so-called "excise tax" not to pay debts or provide revenue for the national welfare, but to punish "noncompliance" with the IRA's requirements. 26 U.S.C. § 5000D (describing "noncompliance periods" that trigger the penalty). Although Congress dubbed the penalty an "excise tax," "Congress's choice of label . . . does not . . . control whether an exaction is within Congress's

[24] Citing a Bloomberg *opinion* article (mistakenly described as a "Bloomberg Law" article) and a journal article predating the IRA, the government says that "[o]utside experts project that each of the manufacturers of the selected drugs have recouped their fixed-cost investments in those drugs" before being selected for price controls. Gov't Br. 70 n.22. As Plaintiffs have explained, however, even if these "projection[s]" by "outside experts" were accurate, because only a miniscule fraction of potential new drugs succeeds in traversing the long, expensive path to market, "companies need to be able to make returns that offset the costs of the numerous experimental drugs that fail." Pl. Br. 7 & nn.1–3. That basic economic reality cannot be ignored.

constitutional power to tax." 567 U.S. at 564; *see also United States v. Constantine,* 296 U.S. 287, 294 (1935) ("If in reality a penalty it cannot be converted into a tax by so naming it"). That principle is crucial because "Congress may not . . . expand its power under the Taxing Clause . . . by labeling a severe financial punishment a 'tax.'" *NFIB*, 567 U.S. at 544. Despite the Supreme Court's warning in *NFIB*, that is precisely what Congress did in the IRA.

The government appears to agree that the controlling test for the scope of the taxing power is the "functional approach" set forth in *NFIB*, 567 U.S. at 561–75. Thus, "the essential feature of any tax" is that it "produces at least some revenue for the Government." *Id*. at 564; *accord Liberty Univ., Inc. v. Lew*, 733 F.3d 72, 97 (4th Cir. 2013). The government gives this requirement short shrift, claiming that the "excise tax" is "capable of raising significant revenue, on its face." Gov't Br. 72. But on its face, the "excise tax" is a draconian penalty of up to 1,900% per sale. No manufacturer could or would dare to incur that "unbearable" sanction. Dkt. 29-5, Staff Decl. at PageID 191 ¶ 16. Indeed, that is precisely what the CBO and the Joint Committee on Taxation concluded: the "excise tax" will raise *zero* revenue. *See supra* at 23. The government responds by attempting to downplay the significance of those expert analyses, *see* Gov't Br. 71–72, but it does not offer any contrary evidence, and the Supreme Court itself relied on the CBO's analysis in *NFIB*, 567 U.S. at 564 (citing CBO projection that "the payment is expected to raise about $4 billion per year by 2017").

The government also relies heavily on dicta in a case that has been superseded by the test set forth in *NFIB*. *See* Gov't Br. 71 (citing *United States v. Sanchez*, 340 U.S. 42, 44 (1950)); *id.* at 73 (quoting the same sentence from *Sanchez* again). In *Sanchez*, the government sought to collect $8,701.65 in taxes and interest based on a violation of the Marihuana Tax Act, which imposed a tax of $100 per ounce on transfers of marijuana to persons who had not themselves paid

a "special tax" and completed registration requirements. 340 U.S. at 43–44. From the outset, then, it was clear that the tax in *Sanchez* would "produce[] at least some revenue for the Government." *NFIB*, 567 U.S. at 564. The Court also relied on a Senate report indicating that one of Congress's chief purposes in enacting the Marihuana Tax Act was "the development of a plan of taxation which will raise revenue." *Sanchez*, 340 U.S. at 43. In its brief to the Court, the government confirmed that "the marihuana transfer tax . . . has produced some revenue," including "$5,554.90" of revenue "[i]n the fiscal year ending June 30, 1949" (about $70,000 in today's dollars). Brief for the United States at 31 n.2, *Sanchez*, 340 U.S. 42 (No. 81), 1950 WL 78340. Thus, while the Court stated that a tax "does not cease to be valid merely because it regulates, discourages or even definitely deters the activities taxed," that statement went considerably farther than was necessary to resolve the case. And in any event, the Supreme Court clarified in *NFIB* that generating at least "some revenue" is "essential." 567 U.S. at 564.

Moreover, even assuming *arguendo* that the IRA's "excise tax" could somehow raise revenue, it bears another hallmark of a coercive penalty under *NFIB*: it "impose[s] an exceedingly heavy burden." *Id*. at 565. There can be no doubt that the "excise tax," with its penalties of up to 19 times revenue, is exceedingly burdensome by any measure. In response, the government merely repeats its canards about the IRS guidance "clarif[ying] . . . the calculation" of the "excise tax" (when in fact the guidance simply restated the statutory formula) and the "excise tax" supposedly applying only to "Medicare sales," rather than to all U.S. sales (as the statute provides). Gov't Br. 73 n.23. Yet the government cannot deny that the "excise tax" bears no resemblance to the modest individual-mandate penalty in *NFIB*. *See NFIB*, 567 U.S. at 566. It is instead the epitome of a "prohibit[ive]" financial punishment. *Id.* (quotation marks omitted).

The government also misses the mark when it claims that the IRA's non-compliance penalty "looks like a tax in many respects." Gov't Br. 71 (quoting *NFIB*, 567 U.S. at 563). In *NFIB*, the exaction was not only found in the Internal Revenue Code and enforced by the IRS—features that, by themselves, would be empty formalisms—but also clearly functioned as an integral part of the broader tax system. For instance, the amount of the exaction was "determined by such familiar factors as taxable income, number of dependents, and joint filing status." 567 U.S. at 563–64. Here, in contrast, the rate of the so-called "excise tax" is determined by the length of the period of noncompliance. *See* 26 U.S.C. § 5000D(d). The "excise tax" does not "look like a tax" except in the most superficial ways; in every substantive respect, it is a steep, escalating penalty. Furthermore, while the government claims that the "excise tax" will be "paid like a tax" rather than "exacted by [HHS] inspectors after ferreting out willful malfeasance," Gov't Br. 72, here that is a false dichotomy; both the IRA and CMS's own guidance make clear that the HHS will monitor manufacturers for noncompliance and "refer" them to the IRS for enforcement of the penalty. *See* 42 U.S.C. § 1320f-5(a)(6); Revised Guidance at 91–92, 167. In sum, the "excise tax" is nothing more than an attempt by Congress to "expand its power . . . by labeling a severe financial punishment a 'tax.'" *NFIB*, 567 U.S. at 544.

2. The only other enumerated power that the government suggests might support the "excise tax" is the Commerce Clause. The Commerce Clause authorizes Congress "[t]o regulate Commerce . . . among the several States." Art. I, § 8, cl. 3. According to the government, "the only Commerce Clause question potentially raised by this case" is whether "the sale of prescription drugs to Medicare beneficiaries substantially affects interstate commerce." Gov't Br. 74. But after *NFIB*, that is *not* the only relevant question: courts must also ask whether the law at issue "*regulates*" commerce (which is permissible within certain bounds) or "*compel[s]*" it (which is

never permissible under any circumstances). *NFIB*, 567 U.S. at 555–56; *see also id.* at 550 (noting that the power to "regulate" commerce does not include the power to "create" commerce that does not already exist). Here, the "excise tax" does more than merely regulate preexisting commerce; it compels manufacturers to agree to a new transaction from which they would strongly prefer to "abstain." *Id*. at 571. By penalizing a manufacturer's *failure* to agree to "provide access" to its drug at the government's chosen price, the IRA runs afoul of *NFIB*'s limiting principle: Congress may regulate only commercial "activity," not "inactivity." *Id.* at 555 ("[T]he distinction between doing something and doing nothing would not have been lost on the Framers").

The government's only comeback is to assert that the "excise tax" is nominally "tied to *sales* of selected drugs," and that "sales are quintessential commercial activity." Gov't Br. 74–75. As Plaintiffs have explained, however, the "excise tax" is designed to *prevent* any such sales and replace them with a new course of dealing with CMS. *See* Pl. Br. 44–45. Because the "excise tax" is in reality a penalty for failing to do business with the government on the government's terms—not a genuine sales tax—it is an impermissible compulsion of commerce. The "tax" finds no home in any of Congress's enumerated powers and must be held unconstitutional.

CONCLUSION

The Court should grant summary judgment in favor of Plaintiffs on all of their claims.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 10, 2024, a true and correct copy of the foregoing Combined Opposition and Reply in Support of the Motion for Summary Judgment was electronically filed with the Clerk of Court using the CM/ECF system which will send notification to all counsel of record.

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